

IIS FUNCTIONAL GUIDE, VOL.2

CDC ENDORSED DATA ELEMENTS

1.25.2019



AIRA
AMERICAN IMMUNIZATION
REGISTRY ASSOCIATION

EXECUTIVE SUMMARY

Millions of patient records and immunization histories are exchanged electronically between providers and immunization information systems (IIS) daily.

A vast majority of IIS support bidirectional data exchange. This enables data to flow from the provider's electronic health record (EHR) to the IIS and from the IIS back to the EHR; providers submit vaccination events to the IIS and query the IIS for a consolidated patient record and forecast for clinical decision support.

None of this is possible without the knowledge, best practices, and standards developed by the immunization community and its many partners and stakeholders, which include EHRs and other technology partners as well as peers in public health, pharmacies, school systems, CDC (Centers for Disease Control and Prevention) and the broader health IT community.¹

As the health IT landscape matures and the push for interoperability across data systems continues to grow, the immunization community must strive for further adoption of standards to ensure that EHR-to-IIS interoperability continues to be streamlined. While the immunization community has accomplished an impressive amount of work to standardize data exchange, there is more work to be done. It is vitally important that data elements used across multiple systems carry the same meaning. Inconsistencies across systems in how data is submitted, collected, and used exist even where data element definitions seem obvious. These inconsistencies can lead to data quality issues and/or misinterpretations of outcomes.

The IIS Functional Guide Volume 2: CDC Endorsed Data Elements is the second in a series of guides aimed at clarifying the capabilities and requirements a system needs to support critical business functions. The first volume focused on Query and Response. It is anticipated that future volumes will continue the important work of aligning best practices and technical resources to inform the immunization community as they enhance and optimize their systems. The Functional Guide series leverages the collective expertise of the IIS community as well as national standards and published guidance to inform implementation of established best practices and standards.

¹ In this guide, immunization community refers to IIS, immunization programs, EHRs and other technology partners, peers in public health, pharmacies, school systems, CDC, and the broader health IT community.

The IIS Functional Guide Volume 2: CDC Endorsed Data Elements focuses on clarifying definitions and attributes of a select set of CDC endorsed data elements. A workgroup of subject matter experts (SMEs) convened over the course of 10 months to review the [IIS Functional Standards v4.0²](https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-0.html) and [CDC Endorsed Data Elements³](https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html) and identify those data elements most in need of clarification. This subset of data elements (35) is presented in the guide with expanded information to clarify definitions, describe areas of challenge experienced by IIS and EHRs, and document expectations for data submitters and receivers. The goal of this guide is to bridge gaps in documentation and address some of the interoperability challenges facing the IIS community today.

It is important to note that this project was limited in scope to focus only on high-priority data elements due to time and resources available. Although the remaining data elements are lower in priority, there may still be some value in defining and documenting their attributes as part of a future project.

² <https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-0.html>, published August 2017

³ <https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html>



TABLE OF CONTENTS

EXECUTIVE SUMMARY	i		
1 INTRODUCTION	1		
1.1 Functional Guide Purpose	4		
2 SCOPE	5		
2.1 How to Use this Guide	7		
2.2 Overall Expectations	7		
3 CORE CONCEPTS	8		
4 DATA ELEMENTS	11		
5 DATA ELEMENT DEFINITIONS	14		
6 SELECTED DATA ELEMENTS	19		
7 GROUP: PATIENT	21		
7.1 Patient Gender	22		
7.2 Race	24		
7.3 Ethnicity	25		
7.4 Mother's Name: Maiden Last	26		
7.5 Patient Birth Order	28		
8 GROUP: PATIENT IDS	30		
8.1 Patient ID	31		
8.2 Patient ID: Type	33		
8.3 IIS Patient ID	34		
9 GROUP: CONTACT INFORMATION	36		
9.1 Patient Address: County of Residence	37		
9.2 Patient Birth State	39		
9.3 Patient Telephone Number	40		
9.4 Patient Telephone Number Type	42		
9.5 Responsible Person Name: First, Middle, Last	43		
9.6 Responsible Person Relationship to Patient	44		
10 GROUP: STATUS/ PROTECTION	46		
10.1 Patient Status Indicator – Jurisdiction Level	47		
10.2 Patient Status Indicator – Provider Level	49		
10.3 Protection Indicator	51		
10.4 Protection Indicator Effective Date	53		

TABLE OF CONTENTS

11	GROUP: VACCINATION	54
11.1	Vaccine Product	55
11.2	Vaccination Event Record Type	57
11.3	Vaccine Manufacturer Name	60
11.4	Vaccine Lot Number	62
11.5	Vaccine Route of Administration	64
11.6	Vaccine Site of Administration	65
11.7	Dose Level Eligibility	66
11.8	Vaccine Funding Source	68
11.9	Vaccine Information Statement	70
11.10	Vaccine Information Statement Given Date	72
11.11	Contraindications/Precautions	75
11.12	Exemptions/Refusals Reason	77
12	GROUP: FACILITY	79
12.1	Administered at Location	80
12.2	Responsible Organization	82
12.3	Sending Organization	83
13	LIMITATIONS & GAPS	85

APPENDICES

APPENDIX A	ABBREVIATIONS/ACRONYMS	88
APPENDIX B	MASTER DATA ELEMENTS TABLE	89
APPENDIX C	DATA ELEMENTS MAPPED TO FUNCTIONAL STANDARDS	95
APPENDIX D	ACKNOWLEDGMENTS	101



1

INTRODUCTION



“If sending and receiving systems are not developed and configured to adhere to a common and consistent set of vocabularies, code sets and value sets, the users of those systems will have difficulty with interoperability.”

—Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap

1 INTRODUCTION

One of the pain points most frequently heard in conversations about IIS (immunization information systems) and EHR (electronic health record system) interoperability is the variability in how some data fields are defined and used.

These differences, no matter how subtle, can have a significant impact on data submission and data integrity. While the IIS community has published a wealth of best practice and technical documentation to support IIS operations and technical solutions, there remains a need to clarify definitions and usage of data elements that are core to IIS. As stated in [Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap](#), “Consistent and shared ways to represent the meaning of clinical concepts and terminology are necessary to support clinical care, research, quality measurement and clinical decision support.”⁴

In early 2018, the American Immunization Registry Association, or AIRA, launched a project to develop the second volume of the Functional Guide series. This second volume provides functional guidance for a select set of CDC endorsed data elements. The endorsed data elements are a published set of key IIS data elements that play a critical role in supporting IIS business functions, as well as efforts to meet the IIS Functional Standards as required by CDC.⁵ The [IIS Functional Standards](#) describe the operations, data quality, and technology needed by IIS to support immunization programs, vaccination providers, and other immunization stakeholders and their immunization-related goals.⁶

A workgroup of subject matter experts (SMEs) was convened, and a project team kicked off a plan to develop the guide. Over the following 10 months, the workgroup and project team reviewed the CDC endorsed data elements, deliberated over pain points and challenges, identified resources and documentation to support their work, and prepared this guide for publication. Individual participants are listed in [Appendix D. Acknowledgments](#).

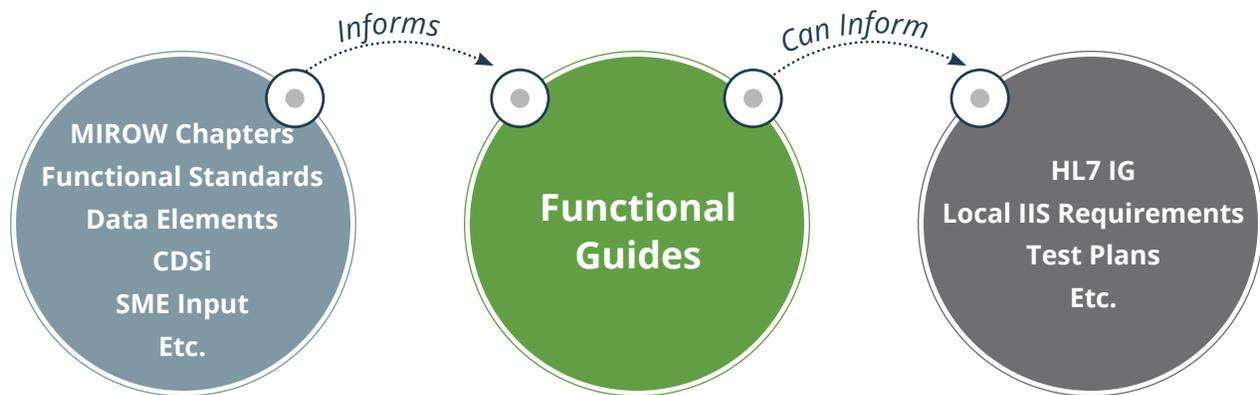
⁴ <https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>

⁵ <https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html>

⁶ <https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-0.html>

1.1 FUNCTIONAL GUIDE PURPOSE

A functional guide does not dictate that a system must provide certain functionality; rather, it defines the requirements if a system chooses to supply certain functionality. The following diagram shows the relationship between best practice guidance (such as Modeling of Immunization Registry Operations Workgroup Chapters) and technical specifications (such as the HL7 Implementation Guide).





SCOPE

2



2 SCOPE

The IIS Functional Guide Volume 2: CDC Endorsed Data Elements focuses on clarifying definitions of a select set of CDC endorsed data elements.

A workgroup of SMEs convened over the course of 10 months to review the [IIS Functional Standards v4.0](#)⁷ and [CDC Endorsed Data Elements](#)⁸ and identify those data elements most in need of clarification. The workgroup considered the following in their review:

- Is the definition clear?
- Is the data element used differently between trading partners, such as EHRs and IIS?
- Does the data element cause confusion among trading partners?
- Are there known data quality issues related to the data element?
- Which data elements require frequent explanation to data end users and trading partners?

The complete CDC Endorsed Data Elements list has 68 data elements; the workgroup, along with the AIRA project team, ultimately selected 35 data elements for presentation in this guide. The selected data elements were chosen because it was clear that clarification was needed on their purpose and usage. The workgroup found gaps in documentation and clarity around how or why these data elements were valuable and best utilized. The remaining 33 data elements are no less important and were considerably clearer, though it may still be valuable to expand this volume at a later date to include all 68 data elements.

This guide will cover the CDC terms and definitions, expanded information to clarify definitions and usage details, challenges experienced among IIS and EHRs exchanging the data elements, and expectations for IIS, EHRs, and Vital Records systems. The goal of this guide is to bridge gaps in documentation and address some of the interoperability challenges facing the immunization community today.

⁷ <https://www.cdc.gov/vaccines/programs/iis/functional-standards/func-stds-v4-0.html>

⁸ <https://www.cdc.gov/vaccines/programs/iis/core-data-elements.html>



2.1 HOW TO USE THIS GUIDE

This guide is best used as a reference, providing clarity and aligning technical specifications to best practices guidance. Wherever possible, the guide reuses terms and definitions from existing resources rather than creating new terms for the same concepts.

This guide is intended for both technical and programmatic audiences. It is designed to support any trading partner working with IIS as well as the broader immunization community.

2.2 OVERALL EXPECTATIONS

This guide makes the following assumptions of IIS and trading partners:

- The [HL7 2.5.1 Rel. 1.5 Implementation Guide and Addendum](https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html)⁹ (hereafter referred to as HL7 IG) is the referenced Health Level 7 standard expected to be in use across the IIS and EHR communities.
- The [CDC code value sets](https://www.cdc.gov/vaccines/programs/iis/code-sets.html)¹⁰ are the standard expected to be in use across the IIS and EHR communities.
- Local requirements for data exchange are minimized to the extent they can be, given local policy and rule.
- Data exchanged between trading partners that will not be utilized by the receiving system should be gracefully ignored. This also means not sending errors on data the receiving system does not intend to store.
- IIS shall store all CDC endorsed data elements received from trading partners.

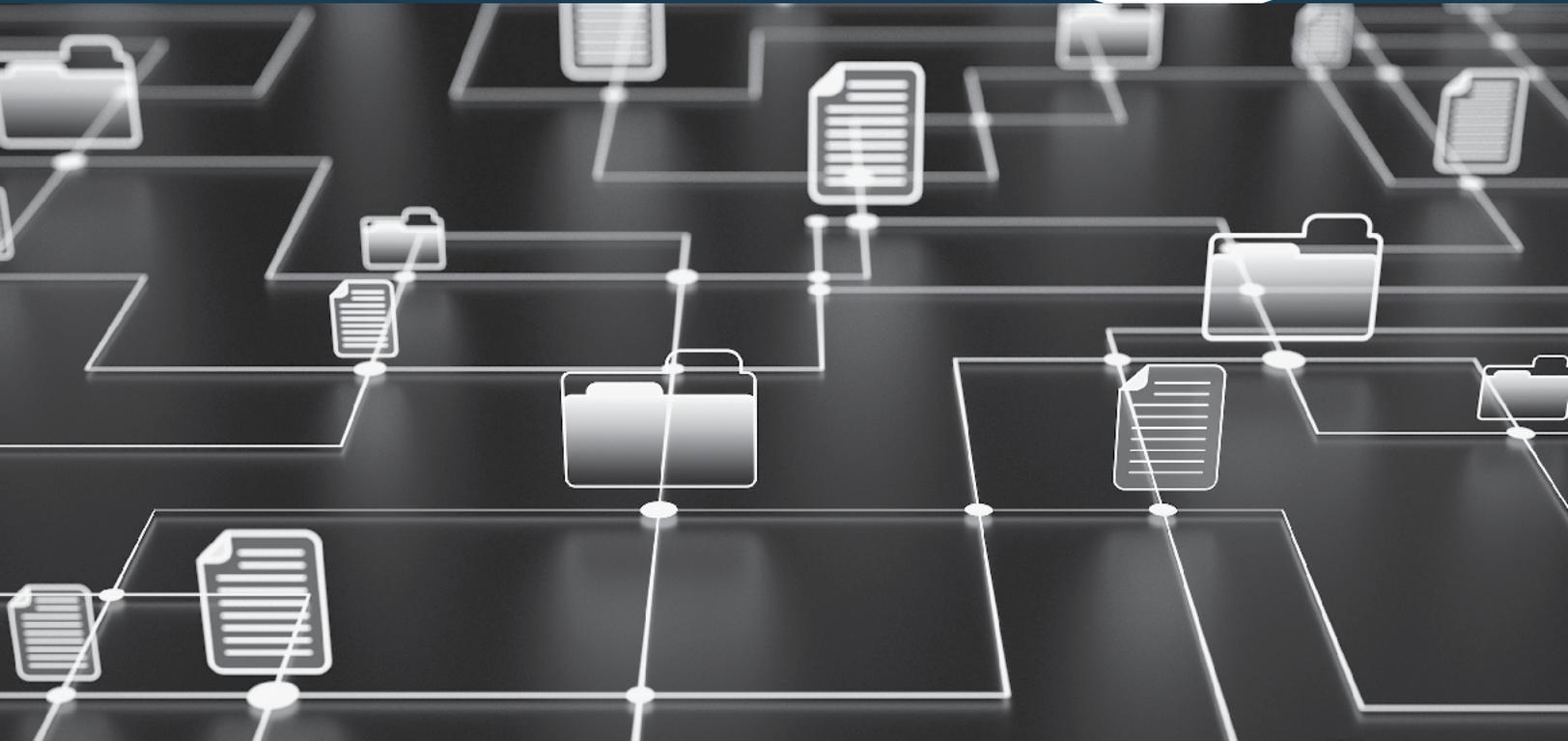
⁹ <https://www.cdc.gov/vaccines/programs/iis/technical-guidance/hl7.html>

¹⁰ <https://www.cdc.gov/vaccines/programs/iis/code-sets.html>



3

CORE CONCEPTS



3 CORE CONCEPTS

This guide leverages some of the same core concepts described in the Functional Guide Volume 1: Query and Response. The conformance keywords are the same, but the action words are new.

Conformance keywords¹¹ and action words describe the requirements needed to meet optimal IIS functionality. Keywords pair with action words to describe how a system treats a specific CDC endorsed data element (e.g., An EHR **shall submit** patient first name, or an IIS **shall store** patient first name).

A note on conformance: in this guide, conformance is specific to the expectations outlined herein. For example, “An IIS shall store patient first name” is a conformance statement.

CONFORMANCE KEYWORD	MEANING
SHALL or SHALL HAVE THE ABILITY TO	Indicates a mandatory requirement to be followed or implemented 100% of the time in order to conform. Or, have the ability to conform across all clinical settings, workflows, and/or use cases when data is available/present. Synonymous with “is required to” and “must.”
SHOULD or SHOULD HAVE THE ABILITY TO	This word and the adjective “RECOMMENDED” mean that there may exist valid reasons in particular circumstances to ignore a particular item, but the full implications must be understood and carefully weighed before choosing a different course.
MAY or MAY HAVE THE ABILITY TO	Indicates an optional or permissible requirement to be followed or implemented. Synonymous with “is permitted.” These requirements serve to enhance data quality and interoperability above and beyond the required functionality.
SHOULD NOT	This phrase and the phrase “NOT RECOMMENDED” mean that there may exist valid reasons in particular circumstances when the particular behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
SHALL NOT	Indicates a prohibited action. Synonymous with “prohibited” and “must not.”

¹¹ The basis of these terms is from RFC 2119 with further refinement to the purpose of the functional guide. <https://tools.ietf.org/pdf/rfc2119.pdf>

ACTION WORD	MEANING
ASSIGN	Indicates an action to associate or link data elements.
DERIVE	Indicates an action of obtaining information or data from a specified source.
GENERATE	Indicates an action to create, as in generate a unique ID.
IGNORE	Indicates an action to disregard, as in not to validate or return feedback on.
STORE	Indicates an action of saving received data so it can be retrieved at a later time if needed.
SUBMIT	Indicates an action of sending the data to or entering the data into a receiving system. Synonymous with "send."
SUPPORT	Indicates an action to provide assistance or maintain.
UTILIZE	Indicates a potential way the IIS use the data.





4

DATA ELEMENTS



4 DATA ELEMENTS

The **CDC endorsed data elements** represent the minimally required data needed in an IIS to help it achieve the IIS Functional Standards as described by the CDC. Together, the data elements and the Functional Standards provide a plan for achieving an optimally functioning IIS.¹²



**PATIENT
DEMOGRAPHICS**



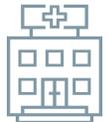
**VACCINATION
EVENT**



¹² <https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html>

DATA ELEMENTS EXAMINED IN THIS GUIDE

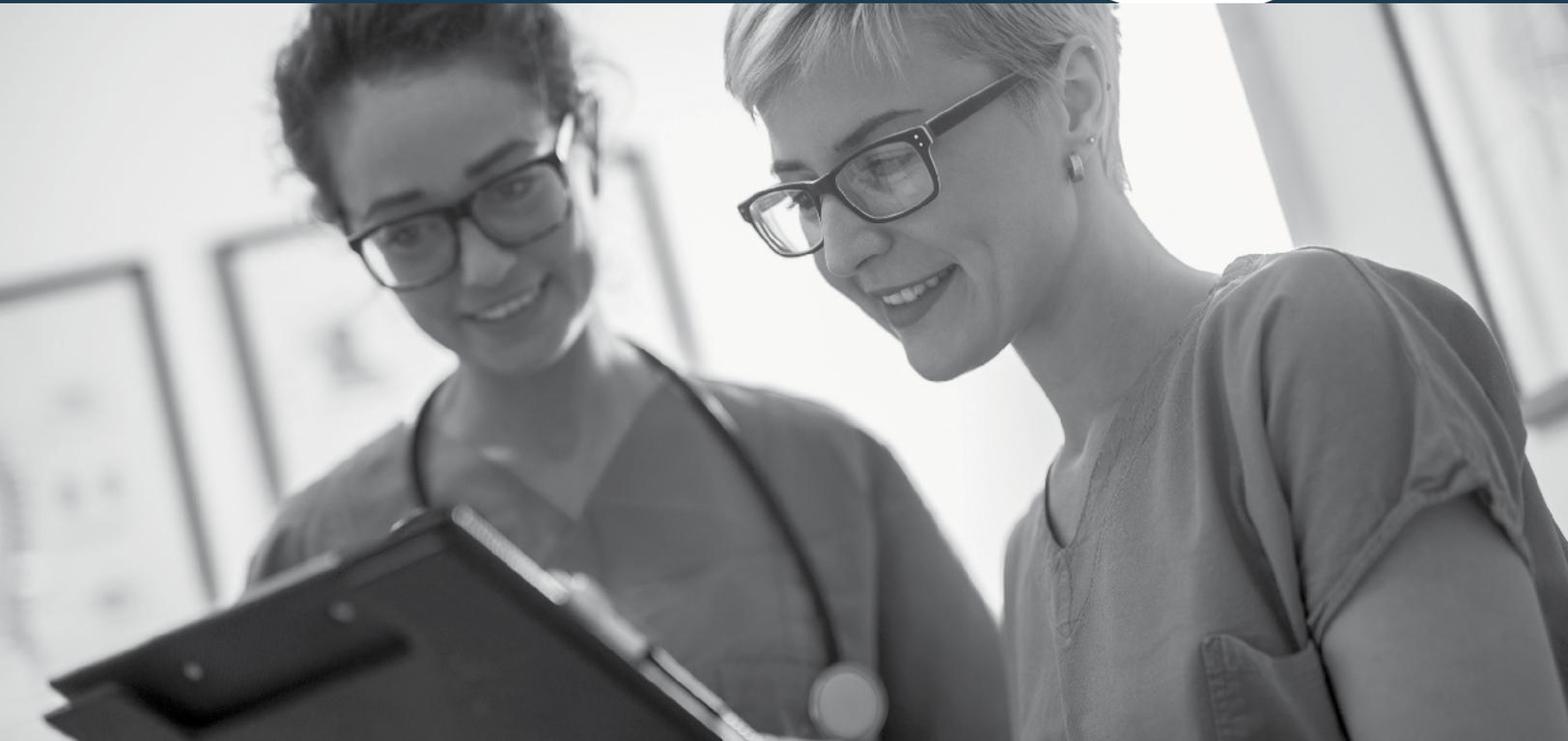
The data elements are presented below in groupings related to clinical workflow and/or how data is exchanged between trading partners. The 35 data elements selected for expanded review in this Functional Guide are noted in highlighted text below. The list of all 68 CDC data elements and their definitions can be found in [Chapter 5: Data Element Definitions](#) (pages 14-18).

PATIENT DEMOGRAPHICS		PATIENT Pages 21–29	<ul style="list-style-type: none"> ■ Patient Gender ■ Race ■ Ethnicity 	<ul style="list-style-type: none"> ■ Mother’s Name: Maiden Last ■ Patient Birth Order
		PATIENT IDS Pages 30–35	<ul style="list-style-type: none"> ■ Patient ID ■ Patient ID: Type 	<ul style="list-style-type: none"> ■ IIS Patient ID
		CONTACT INFORMATION Pages 36–45	<ul style="list-style-type: none"> ■ Patient Address: County of Residence ■ Patient Birth State ■ Patient Telephone Number ■ Patient Telephone Number Type 	<ul style="list-style-type: none"> ■ Responsible Person Name <ul style="list-style-type: none"> — First — Middle — Last ■ Responsible Person Relationship to Patient
		STATUS/ PROTECTION Pages 46–53	<ul style="list-style-type: none"> ■ Patient Status Indicator – Jurisdiction Level ■ Patient Status Indicator – Provider Level 	<ul style="list-style-type: none"> ■ Protection Indicator ■ Protection Indicator Effective Date
VACCINATION EVENT		VACCINATION Pages 54–78	<ul style="list-style-type: none"> ■ Vaccine Product ■ Vaccination Event Record Type ■ Vaccine Manufacturer Name ■ Vaccine Lot Number ■ Vaccine Route of Administration ■ Vaccine Site of Administration 	<ul style="list-style-type: none"> ■ Dose Level Eligibility ■ Vaccine Funding Source ■ Vaccine Information Statement ■ Vaccine Information Statement Given Date ■ Contraindications/Precautions ■ Exemptions/Refusals Reason
		FACILITY Pages 79–84	<ul style="list-style-type: none"> ■ Administered at Location ■ Responsible Organization ■ Sending Organization 	



**DATA ELEMENT
DEFINITIONS**

5



5 DATA ELEMENT DEFINITIONS

The complete CDC Endorsed Data Elements list is presented here, along with each element's CDC definition.

The starred data elements reflect the 35 selected for expanded review in this guide.

DATA ELEMENT	DEFINITION
 PATIENT	
Patient Name: First	The patient's first name.
Patient Name: Middle	The patient's middle name.
Patient Name: Last	The patient's last name.
Patient Alias Name: First	The first name of a patient's alternate or also-known-as name.
Patient Alias Name: Middle	The middle name of a patient's alternate or also-known-as name.
Patient Alias Name: Last	The last name of a patient's alternate or also-known-as name.
Patient Date of Birth	The patient's date of birth.
★ Patient Gender	The patient's gender.
★ Race	The patient's race.
★ Ethnicity	The ancestry of the patient.
Patient Primary Language	The patient's primary language.
Mother's Name: First	The first name of the patient's mother.
Mother's Name: Middle	The middle name of the patient's mother.
Mother's Name: Last	The last name of the patient's mother.
★ Mother's Name: Maiden Last	The last name under which the mother was born (i.e., before marriage).
Patient Multiple Birth Indicator	Whether the patient was part of a multiple birth (yes/no).
★ Patient Birth Order	When a patient was part of a multiple birth, a number is defined in this element (e.g., 1, 2, 3).
History of Disease/Titer	The disease the patient is expected to be immune to on the basis of serological or clinical evidence.
Date of History of Disease/Titer	The date/time of patient immunity due to serological or clinical evidence was observed.

DATA ELEMENT	DEFINITION
 PATIENT IDS	
★ Patient ID	Unique identifier assigned by IIS-AO (data source) to each patient.
★ Patient ID: Type	The ID type (e.g., medical record number, birth certificate ID) of the associated patient ID.
★ IIS patient ID	The unique identifier assigned by IIS to each patient.
DATA ELEMENT	DEFINITION
 CONTACT INFORMATION	
Patient Address: Street	The street component of the patient's address.
Patient Address: City	The city component of the patient's address.
Patient Address: State	The state component of the patient's address.
Patient Address: Country	The country component of the patient's address.
Patient Address: Zip Code	The ZIP code of the patient's address.
★ Patient Address: County of Residence	The county component of the patient's address.
★ Patient Birth State	State of the birthing facility location.
★ Patient Telephone Number	The patient's phone number.
★ Patient Telephone Number Type	The type of phone number (e.g., home, cell) for each patient telephone number.
Patient E-mail Address	The patient's email address.
★ Responsible Person Name: First	The first name of the person responsible for the patient.
★ Responsible Person Name: Middle	The middle name of the person responsible for the patient.
★ Responsible Person Name: Last	The last name of the person responsible for the patient.
★ Responsible Person Relationship to Patient	The actual personal relationship that the responsible person has to the patient.

DATA ELEMENT	DEFINITION
 STATUS / PROTECTION	
★ Patient Status Indicator-Jurisdiction Level	The patient/geographic jurisdiction status determined from address information when the patient's address within the jurisdiction is known.
★ Patient Status Indicator-Provider Level	The current active/inactive status of the patient in relation to the provider organization.
Reminder/Recall Status	Whether or not a person wishes to be contacted in a reminder or recall situation.
Reminder/Recall Effective Date	The effective date for the patient's reminder/recall status.
★ Protection Indicator	This element identifies whether a person's information may be shared with others, as defined locally.
★ Protection Indicator Effective Date	The effective date for the protection indicator.

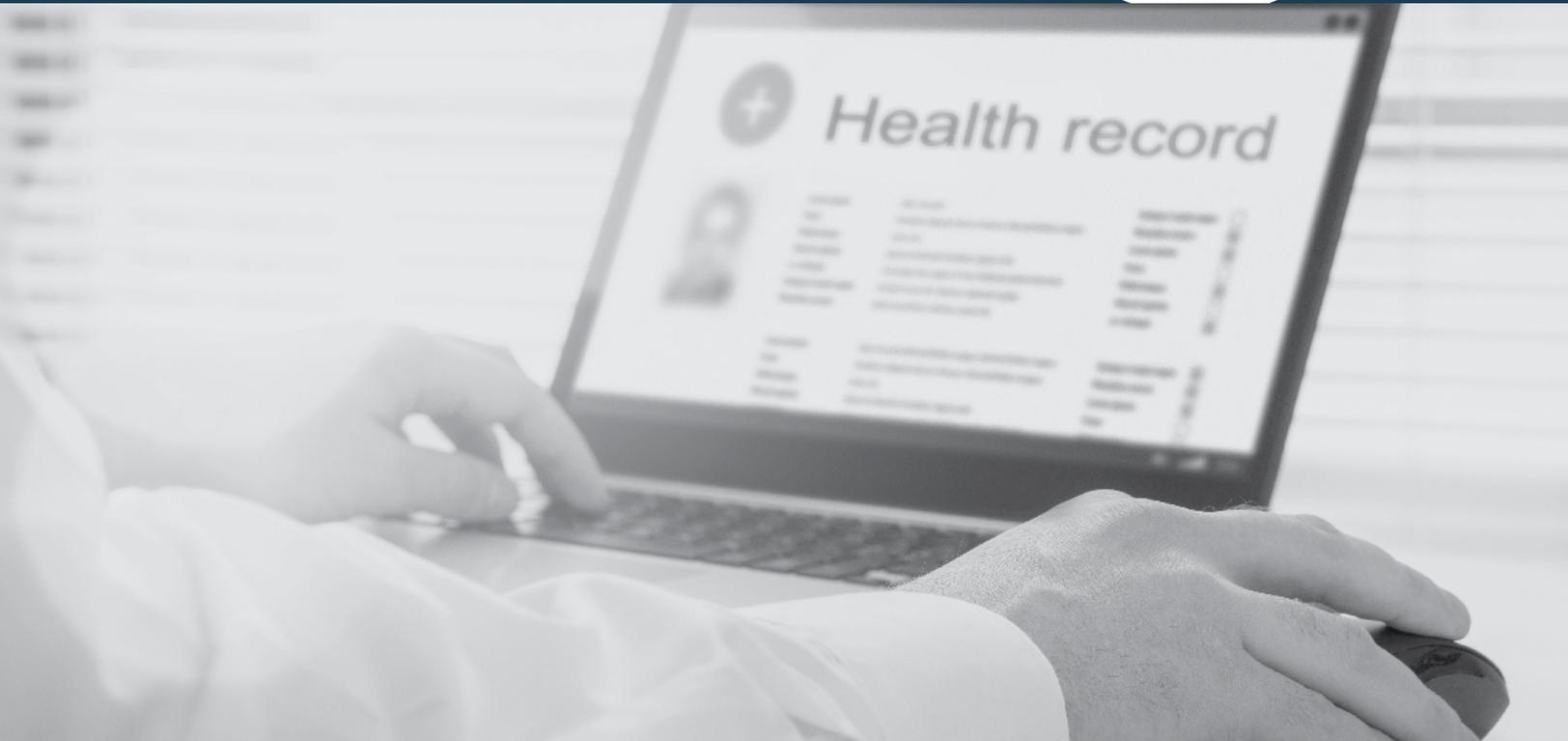
DATA ELEMENT	DEFINITION
 VACCINATION	
★ Vaccine Product	The vaccine type that may be administered, historical, or refused and is messaged using the NDC or CVX code sets.
Vaccination Administration Date	The date the vaccination event occurred.
★ Vaccination Event Record Type	Indicates whether the vaccination event is based on a historical record or was given by the administered at location.
★ Vaccine Manufacturer Name	The manufacturer of the vaccine that was administered.
★ Vaccine Lot Number	The lot number of the vaccine administered.
Vaccine Expiration Date	The expiration date of the vaccine administered.
Vaccine Dose Volume	The amount of vaccine administered (e.g., .5).
Vaccine Dose Volume Units	The unit of measure of the dose (e.g., ml).
IIS Vaccination Event ID	The unique identifier assigned by IIS to each vaccination event.
Vaccination Event ID	The vaccination event's unique identifier assigned by the submitting system.

DATA ELEMENT	DEFINITION
★ Vaccine Route of Administration	The route of administration.
★ Vaccine Site of Administration	The anatomical site where the vaccine was given.
★ Dose Level Eligibility	The program that should pay for a given immunization, based on the characteristics of the patient and the type of vaccine administered.
★ Vaccine Funding Source	The funding source of the vaccine administered.
★ Vaccine Information Statement	The publication date of the vaccine information statement.
★ Vaccine Information Statement Given Date	The date the VIS information was provided to the patient.
Vaccine Ordering Provider	The identifier of the provider (person) ordering the immunization.
Vaccine Administering Provider Suffix	The professional designation of the person administering the vaccination. (e.g., MD, LPN, RN).
Vaccine Administering Provider	The name of the provider (person) administering the vaccination.
★ Contraindications/Precautions	A reason(s) to consider not giving a patient a vaccine proposed for administration.
Contraindications/Precautions Observation Date	The date/time the patient contraindication or precaution was observed.
★ Exemptions/Refusals Reason	The reason for an exemption/refusal.
Exemptions/Refusals Date	The date that the refusal or deferral was recorded.
DATA ELEMENT	DEFINITION
 FACILITY	
★ Administered at Location	The facility name/identifier of the facility that administered the immunization.
★ Responsible Organization	The identifier of the organization that originated and is accountable for the content of the record.
★ Sending Organization	The identifier of the organization that connects to the IIS and submits the record.



**SELECTED DATA
ELEMENTS**

6



6 SELECTED DATA ELEMENTS

The following data elements were selected by the workgroup for detailed review in this guide. They were chosen with careful consideration and selected based on a recognized need for greater explanation and clarification to ensure consistent use.

The workgroup considered which data elements generated the most discussion and confusion and which were most likely to mean different things depending on the trading partner. For example, the responsible person is typically used by the IIS as a person to contact for reminder/recall. An EHR might consider the responsible person as the one who will pay the bill for the visit. In reality, these could easily be two different people playing two different roles.

The selected data elements are grouped together based either on clinical workflow or area of functionality in the IIS. Each data element section contains the CDC term and definition, how the data element is used, common challenges, and expectations as well as a reference to the related Functional Standards and what happens if the data field is empty or inaccurate. Each section also indicates how trading partners should handle data elements. EHR systems and Vital Records systems are indicated here, but other trading partners that submit data to the IIS are expected to follow this guidance to the extent that they support these data elements.





7

GROUP: PATIENT





7 PATIENT

7.1 PATIENT GENDER



CDC DEFINITION: The patient's gender.

Patient gender is an important demographic used in both matching and deduplication. It is required in nearly all scenarios, whether an external partner is exchanging data with the IIS or submitting a query to the IIS or an end user is looking up a patient in the user interface. Automated matching and deduplication rules rely heavily on this data element as do users in manual merging activities.

In the HL7 IG, patient gender is referred to as Administrative Sex. There are multiple concepts for describing patient gender and patient sex. Administrative sex represents the patient's sex as indicated in any legal documentation, such as birth certificate or identification. Administrative sex may or may not align with birth sex. Birth sex represents the patient's sex at birth. Gender identity represents the patient's individual sense of identification with a gender. While IIS are most likely to track just one patient gender concept (administrative sex), EHRs and other sending systems may track multiple concepts. During an onboarding process with a new EHR system, IIS staff can confirm with both the EHR and the provider organization which patient gender concept is being sent. It is important to note, as well, that these concepts can change over time for an individual patient.

As of 2018, California, Oregon, New York, Washington, Washington, D.C., and Maine have passed legislation to legally recognize a third or non-binary gender option.¹³ It is anticipated that EHRs and IIS (and other health information trading partners) will soon start to accept a code for patient gender of non-binary; it will become important for all trading partners to recognize and use the expanded value set.

IIS data users may assess coverage or up-to-date rates by gender. Patient gender may be used in clinical decision support to forecast immunizations due or past due.

¹³ <https://transequality.org/issues/resources/understanding-non-binary-people-how-to-be-respectful-and-supportive>

CHALLENGES:

- Some sending systems and trading partners may already support a code for non-binary that might not yet be recognized by all IIS.
- At this time, the HL7 IG (HL7 Implementation Guide) supports codes for only female, male, and unknown. It is expected that future versions of the HL7 IG will include an expanded code set.
- Some IIS are already accepting additional codes ahead of the updated HL7 IG.
- **If missing:** Incoming messages via data exchange could be rejected, as it is a required field. If data at rest in the IIS is missing patient gender, this could indicate a data quality or data integrity issue.
- **If inaccurate:** Patient records could be mis-merged or become fragmented. It could affect the results of query or patient lookup via the user interface. If patient gender is inaccurate, it could affect forecasting for vaccines that have gender-specific rules .

EXPECTATIONS:

- IIS should support expansion of the gender code set.
- IIS should support updates (changes) to patient gender from Vital Records systems.
- EHR systems shall submit patient gender.
- EHR systems should support expansion of the gender code set.
- Vital Records systems shall submit patient gender.

EHR Systems
SHALL SUBMIT
Vital Records Systems
SHALL SUBMIT

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.
- **10.0** The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.
- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.

7.2 RACE



CDC DEFINITION: The patient's race.

Patient race may be used to assess population-based immunization rates and/or to identify gaps in access to vaccinations for specific populations or communities. The elimination of all health disparities and achievement of health equity based on race and ethnicity is a [Healthy People 2020](#)¹⁴ goal.

Trading partners may capture race codes from a broader value set and will need to map to the CDC value set for self-reported race, which can be found on [Public Health Information Network Vocabulary and Distribution System \(PHIN VADS\)](#).¹⁵

CHALLENGES:

- If race is not captured in the clinic EHR, it will not be transmitted to the IIS. If the patient declines to indicate or the clinician does not record it, then it cannot be submitted.
- The HL7 IG does not support a code for when the patient declines to answer. This means the IIS cannot determine if the data was not submitted, if it wasn't captured, or if the patient declined to answer.
- **If missing:** Calculating population-based rates, identifying gaps in coverage, etc., would be difficult to do.
- **If inaccurate:** Assessing and improving immunization rates by race could be limited.

EXPECTATIONS:

- IIS shall store one or more race codes per patient if submitted.
- EHR systems shall submit race if known.
- EHR systems shall submit multiple race codes for a patient if multiple race codes are recorded in the EHR.
- Vital Records systems shall submit race if known.

EHR Systems

SHALL SUBMIT if known

Vital Records Systems

SHALL SUBMIT if known

¹⁴ <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>

¹⁵ <https://phinvads.cdc.gov/vads/ViewValueSet.action?id=67D34BBC-617F-DD11-B38D-00188B398520>

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.
- **23.0** The IIS supports vaccine management and quality assurance functions for VFC (Vaccines for Children) and state and local vaccine programs.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.

7.3 ETHNICITY



CDC DEFINITION: The ancestry of the patient.

Patient ethnicity may be used to assess population-based immunization rates and/or to identify gaps in coverage for specific populations or communities. The elimination of all health disparities and achievement of health equity based on race and ethnicity, among other factors, is one of many goals called out in [Healthy People 2020](#).¹⁶ Specifically, the patient ethnicity code indicates if the patient is Hispanic or non-Hispanic.

Ethnicity is one of the fields that IIS are assessed on as part of the [IIS Annual Report \(IISAR\)](#).¹⁷

CHALLENGES:

- If ethnicity is not captured in the clinic EHR, it will not be transmitted to the IIS. If the patient declines to indicate or the clinician does not record it, then it cannot be submitted.
- The HL7 IG does not have a code for when the patient declines to answer. This means the IIS cannot determine if the data was not submitted, if it wasn't captured, or if the patient declined to answer.
- **If missing:** Calculating population-based rates, identifying gaps in coverage, etc. would be difficult to accomplish.
- **If inaccurate:** Assessing and improving immunization rates by ethnicity is limited.

¹⁶ <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>

¹⁷ <https://www.cdc.gov/vaccines/programs/iis/annual-report-iisar/overview.html>

EXPECTATIONS:

- IIS shall store patient ethnicity if submitted.
- EHR systems shall submit ethnicity if known.
- Vital Records systems shall submit ethnicity if known.

IIS FUNCTIONAL STANDARD SUPPORTED:

- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.

EHR Systems

SHALL SUBMIT if known

Vital Records Systems

SHALL SUBMIT if known

7.4 MOTHER'S NAME: MAIDEN LAST



CDC DEFINITION: The last name under which the mother was born (i.e., before marriage).

Mother's maiden name is a high-value data element used in the patient matching and deduplication process. It is one of the few patient demographics that does not change over the course of a lifetime except in very specific scenarios, such as adoption where the mother of the patient is updated to the adoptive mother. Mother's maiden name may be included in submission of vaccination event records by a provider organization, or it may be submitted by a Vital Records system.

Some IIS may prioritize updates to mother's maiden name when received from Vital Records systems. As a data source, Vital Records is likely a better source of this data than other sending systems. Mother's maiden name data is considered a high-risk data field from a security point of view. See: [Security Guidance Considerations for Immunization Information Systems](#).¹⁸



¹⁸ <https://repository.immregistries.org/resource/security-guidance-considerations-for-immunization-information-systems/>

CHALLENGES:

- EHRs, Vital Records systems, school systems, and other exchange partner systems might not capture or submit mother's maiden name as part of the data exchange process.
- As patients age, the likelihood of receiving mother's maiden name decreases.
- Mother's maiden name can change under specific circumstances, such as in the event of an adoption. State policy may vary on this, as might IIS processes for updating patient information originally received from Vital Records systems.
- **If missing:** Patient matching or deduplication may be less effective than if this data element is included.
- **If inaccurate:** Patient matching may be less accurate. If this variable is wrong and leads to patient mis-merging, the patient's record could have more/fewer immunizations and potentially a less accurate record, leading to over- or under-vaccination.

EXPECTATIONS:

- IIS should utilize mother's maiden name for patient matching and deduplication processes when the data is available.
- IIS shall not derive mother's maiden name from the responsible person, as it cannot be determined with certainty that the last name attached to the responsible person is that person's maiden name.
- EHR systems shall not derive mother's maiden name from the responsible person or other contact record.
- EHR systems shall submit mother's maiden name if known.
- Vital Records systems shall submit mother's maiden name if known.

EHR Systems

SHALL SUBMIT if known

Vital Records Systems

SHALL SUBMIT if known

IIS FUNCTIONAL STANDARD SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.

7.5 PATIENT BIRTH ORDER



CDC DEFINITION: When a patient was part of a multiple birth, a number is defined in this element (e.g., 1, 2, 3). Typically received from Vital Records or birthing facility.

Patient birth order is specifically used in the IIS to distinguish one twin (or other type of multiple birth set) from another. This is especially helpful when siblings have similar names, given that most, if not all, of their other demographic information (address, responsible persons, etc.) will also likely be the same. The patient birth order field pairs with another data element, patient multiple birth indicator, which is a yes/no flag indicating that the patient is part of a multiple birth set.

Patient birth order applies only to patients born in the same birth; siblings born in separate births should not be given a birth order.



CHALLENGES:

- This field might not be present for older multiple-birth siblings that have moved into the IIS jurisdiction, since there would have been no opportunity for Vital Records or the local birthing center to submit patient birth order. These patient records are at risk of being merged.
- Even after birth order is received via Vital Records and recorded in the IIS, it may be difficult to identify the correct twin if birth order is not received in subsequent queries.
- **If missing:** The risk of mis-merging records is increased as is the risk that one sibling's record will erroneously receive the dose report of the other sibling's record.
- **If inaccurate:** The risk of fragmented or mis-merged records increases. This can also inadvertently affect forecasting, up-to-date reports, and reminder/recall activities. Unmerging mis-merged records in the IIS is a resource-intensive activity.

EXPECTATIONS:

- IIS shall store patient birth order for patients of a multiple birth.
- IIS should utilize patient birth order for identifying patients that are part of a multiple birth and preventing/resolving merging issues.
- EHR systems shall submit patient birth order if known.
- Vital Records systems shall submit patient birth order.

EHR Systems

SHALL SUBMIT if known

Vital Records Systems

SHALL SUBMIT

IIS FUNCTIONAL STANDARD SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.





8

GROUP: PATIENT IDS



8 PATIENT IDS



8.1 PATIENT ID



CDC DEFINITION: Unique identifier assigned by IIS-AO (authorized organization) to each patient.

The patient ID is generated by the trading partner (IIS-AO¹⁹) system sending data to the IIS. The patient ID is most often an MRN (medical record number) generated by an EHR system. Another example is the birth certificate number generated by Vital Records systems. The patient ID is associated to the patient ID type, which defines the type of ID: MRN, birth certificate number, SSN, etc.

Multiple patient IDs can be submitted to identify a patient; these may include MRN, Medicaid ID, SSN, birth certificate number, other state registry ID, among other identifiers.

When trading partners submit patient ID to the IIS (using HL7 messaging), they also send a patient ID type (MRN, SSN, etc.) and an assigning authority. The assigning authority ensures that an MRN submitted by a provider organization stays linked to that provider organization and distinguishes it from MRNs submitted by other organizations. This is important, as an IIS will store all IDs submitted by trading partners.

The patient ID may be used for matching in the EHR system or receiving system when sent in a query response. IIS may use patient ID for matching and deduplication.

The provider organization may use its patient ID in IIS-generated reports to manage patient populations and assessment.

¹⁹ An IIS-AO is any organization that has an agreement with the IIS that allows for submittal and/or retrieval of the IIS data. See: Consolidating Demographic Records and Vaccination Event Records, MIROW, 8/21/17.

CHALLENGES:

- If a trading partner (EHR or health system) reassigns a previously issued patient ID in its own system, it could affect that system's ability to match back to the correct patient record.
- Some patient IDs are considered sensitive or high risk from a security point of view (such as Social Security number), and access or visibility should be limited in the IIS user interface and in data exchange.
- **If missing:** The data will be rejected by the IIS, and the patient record will not be updated.
- **If inaccurate:** It may affect the ability of the EHR to match the results of a query response back to the correct patient record. It may be unnoticed by the IIS and/or it may impede patient deduplication.

EXPECTATIONS:

- IIS shall store multiple patient IDs, associated with each provider organization submitting data for that patient.
- IIS shall return all the associated patient ID(s) previously submitted by a provider organization for their patient when a query is received for that patient.
- EHR systems may utilize the patient ID sent in the query response to aid in validating the patient match.
- EHR systems shall not assign previously assigned patient IDs to new patients.
- EHR systems shall submit patient ID.
- Vital Records systems shall submit patient ID.

EHR Systems
SHALL SUBMIT
Vital Records Systems
SHALL SUBMIT

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.
- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.

8.2 PATIENT ID: TYPE



CDC DEFINITION: The ID type (e.g., medical record number, birth certificate ID, etc.) of the associated patient.

The patient ID type is used to classify the patient ID sent as part of data exchange. Multiple patient ID types are acceptable and sometimes encouraged to assist in patient identification. ID types frequently submitted include medical record number, birth certificate number, Medicaid ID, and Social Security number.

Some patient ID types have specific utility, such as Medicaid ID which may be used to identify Medicaid patients for Medicaid partners' use of IIS data.

IIS can utilize patient ID type to perform data quality checks based on an expected format (e.g., SSN should not be all same number or consecutive numbers).

CHALLENGES:

- Local policy may dictate what types of IDs can be received and stored. For example, specific rules to accept and store Social Security number or birth certificate number may be defined at the local jurisdiction level.
- **If missing:** Data analysis cannot be performed by ID type.
- **If inaccurate:** The ability of the IIS to validate data is limited. The ability of the IIS to use these data for patient deduplication is limited.

EXPECTATIONS:

- IIS shall store the following patient ID types: birth certificate number, Medicaid number, Medicare number, medical record number, and state registry ID.
- IIS shall store patient ID type with the accompanying patient ID.
- IIS shall send patient ID type(s) anytime patient ID(s) is sent in response to a query.
- EHRs shall submit patient ID type with any patient ID submitted as part of patient demographics in an update or query message.
- Vital Records systems shall submit patient ID type with patient ID; this is expected to be the birth certificate number.

EHR Systems
SHALL SUBMIT
Vital Records Systems
SHALL SUBMIT

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.
- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.

8.3 IIS PATIENT ID



CDC DEFINITION: The unique identifier assigned by IIS to each patient.

The IIS patient ID is generated by the IIS and used as a unique identifier for multiple functions, including matching and deduplication. It may also be used in identifying records where further demographics are not shared, such as communications between local health departments and school districts.

Through merging and deduplication, multiple IIS patient IDs will be consolidated into a single patient record. These previous IIS patient IDs should be stored in the patient record and retained for future auditing needs. They may also be leveraged for searching and matching, mis-merging resolution, and data quality checks.

CHALLENGES:

- IIS patient ID may change through record merging (either automated or manual) or un-merging.
- **If missing:** It may signal a data integrity issue in the IIS, as this is likely a key identifier.
- **If inaccurate:** It may result in fragmented records, mis-merging, or misidentification of patient records.

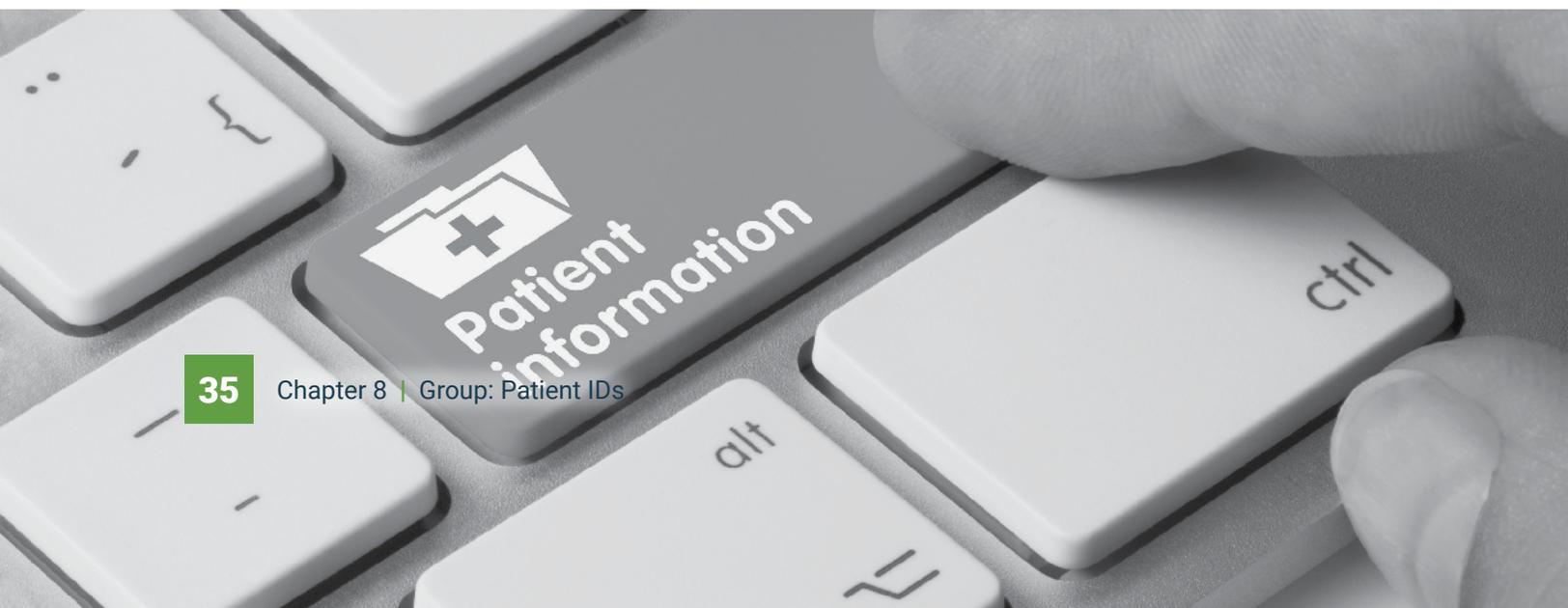
EXPECTATIONS:

- The IIS shall assign a unique IIS patient ID to each patient record.
- The IIS shall store the previous IIS patient IDs with the patient record through any merging and deduplication processes.
- The IIS shall not utilize previously assigned IIS patient IDs.
- The IIS shall send the primary or current IIS patient ID when responding to a query.

EHR Systems
N/A
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.
- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.
- **10.0** The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.
- **14.0** The IIS supports public health response during disease outbreaks.
- **15.0** The IIS supports immunization-related efforts in school settings.
- **16.0** The IIS supports immunization-related efforts in childcare settings.





9

GROUP: CONTACT INFORMATION





9 CONTACT INFORMATION

9.1 PATIENT ADDRESS: COUNTY OF RESIDENCE



CDC DEFINITION: The county component of the patient's address.

The county of residence for a patient applies to the patient's current address as listed in the IIS. County of residence is used to inform coverage and assessment reports as well as broader research, evaluation, and surveillance. County of residence is also used as part of clinic-based coverage and assessment reports.

IIS may use this data element when calculating immunization rates at a geographic level and when identifying areas of under-immunization/pockets of need. IIS may use this during surveillance activities and while monitoring outbreaks. Depending on how local health departments work in partnership with a statewide immunization program, the county of residence may be useful in looking at population and coverage at the county level.

County of residence may be derived from patient address using address standardization software or validation services. In this case, where county of residence is received from trading partners, the IIS should promote the derived county of residence over the submitted county of residence.

CHALLENGES:

- County of residence is often not stored in the EHR system, making it less likely to be submitted.
- If the patient's address changes in the IIS, it is imperative that the county of residence is also updated. This could be challenging if those fields are not linked and if updates to county are not sent from EHR systems.
- **If missing:** Geographic or jurisdiction-level assessment could be difficult to complete.
- **If inaccurate:** Geographic or jurisdiction-level assessment could be skewed.

EXPECTATIONS:

- IIS should utilize address standardization software or validation services to assist in deriving county of residence from current patient address.
- IIS shall ensure that a patient's current county of residence in the IIS corresponds to the patient's current address. As addresses change, the associated county of residence shall be updated as well.
- EHR systems may submit county of residence.
- Vital Records systems may submit county of residence.

EHR Systems
MAY SUBMIT
Vital Records Systems
MAY SUBMIT

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.
- **11.0** The IIS manages patient status at the provider organization and jurisdiction levels.
- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.
- **19.0** The IIS supports reminder and recall activities.



9.2 PATIENT BIRTH STATE



CDC DEFINITION: State of the birthing facility location.

Patient birth state is used to identify the population of patient records in an IIS of people born in that state. This data typically comes only from Vital Records systems. Patient birth-state data in the IIS may be limited by the fact that it comes only from the local Vital Records system. Records for patients in the IIS not born in-state and not submitted via Vital Records would not be expected to have this field populated.

Regardless of whether a patient is born in-state or not, the local public health authority or jurisdiction is still responsible for ensuring access to vaccines and improving up-to-date rates for all individuals within its jurisdiction.

Limited examples or evidence of how and if this data element is used by IIS were found.

CHALLENGES:

- It is unlikely, especially with older children and adults, that EHRs or other sending systems would know and/or submit patient birth state when reporting a vaccination event.
- Not all children residing in an IIS jurisdiction were born in that same jurisdiction. For those patients, the actual birth state is rarely (if ever) known since it is not submitted by EHRs.
- **If missing:** The IIS would be unable to assess the population of patients in the IIS who were born in-state.
- **If inaccurate:** It could signal an issue with the vital records data import.

EXPECTATIONS:

- EHR systems may submit patient birth state.
- Vital Records systems shall submit patient birth state.

IIS FUNCTIONAL STANDARD SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.

EHR Systems

MAY SUBMIT

Vital Records Systems

SHALL SUBMIT

9.3 PATIENT TELEPHONE NUMBER



CDC DEFINITION: The patient's phone number.

Patient telephone number is an important piece of data used in patient matching, in both automated matching processes and manually matching. Patient telephone number may also be used for reminder/recall activities such as text reminders. Patient telephone number is a repeating field in the HL7 IG allowing a provider organization to submit all known and current phone numbers for a patient.

Consolidating and deduplicating patient telephone number across submissions from multiple trading partners requires careful consideration to determine which telephone number should be designated as primary.

Patient telephone number is also used to authenticate individuals who are requesting their own or their children's records through consumer access.

Patient telephone numbers within the IIS are used to support the National Immunization Survey (NIS) as well as the NIS-IIS match project designed to compare vaccine coverage rates using different methodologies.

CHALLENGES:

- Children will often receive reminders, outreach, and follow-up on a parent or guardian’s phone. As patients age, they may have their own phone, at which point the IIS must figure out how to differentiate between the actual patient phone number and the phone number of the patient’s parent or guardian.
- If a patient telephone number is updated in an EHR, it is unlikely that the updated telephone number would be sent to the IIS until a vaccination event is recorded in the EHR system.
- The HL7 IG does not support a method for reporting that a patient telephone number is not current or incorrect. This means that outdated telephone numbers may continue to exist in the IIS even after a new telephone number is submitted.
- **If missing:** It may limit reminder/recall activities where phone or text is used. It may also impact follow-up with a patient during a vaccine recall or vaccine-preventable disease outbreak/surveillance activities.
- **If inaccurate:** The patient’s current phone number might be updated incorrectly. It could also limit the ability of the IIS to match patient records either automatically or manually. For reminder/recall projects, inaccurate phone numbers may expend resources not otherwise needed if accurate.

EXPECTATIONS:

- IIS shall store patient telephone number received with a newly administered immunization as the current or primary phone number.
- IIS shall store multiple patient telephone numbers if received, indicating most recently submitted as primary.
- EHR systems shall submit patient telephone number if known.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARD SUPPORTED:

- **19.0** The IIS supports reminder and recall activities.

9.4 PATIENT TELEPHONE NUMBER TYPE



CDC DEFINITION: The type of phone number (e.g., home, cell) for each patient telephone number.

Patient telephone number type indicates if the phone number is a mobile number, home number, work number, etc. IIS business rules determine how phone numbers are deduplicated and updated.

CHALLENGES:

- **If missing:** If patient telephone number type is missing, the IIS could reject incoming data or assign a default phone type which might be inaccurate.
- **If inaccurate:** If patient telephone number type is inaccurate, the patient record could be updated with an incorrect phone number, which could impact patient matching and reminder/recall activities.

EXPECTATIONS:

- IIS shall store telephone number type with the phone number.
- EHR systems shall submit telephone number type, if patient telephone number is submitted.
- EHR systems may submit multiple patient telephone numbers.

IIS FUNCTIONAL STANDARD SUPPORTED:

- **19.0** The IIS supports reminder and recall activities.

EHR Systems
SHALL SUBMIT
Vital Records Systems
N/A



9.5 RESPONSIBLE PERSON NAME: FIRST, MIDDLE, LAST



CDC DEFINITION: The first (middle, last) name of the person responsible for the patient. Multiple names for the same person are allowed.

Responsible person name (first, middle, last) is used in a variety of ways in IIS. It is useful in matching and/or resolution of possible duplicate patient records. It may be leveraged for reminder/recall activities and for outreach to parents and guardians of patients who are past due for immunizations.

A patient record in the IIS may have one or more responsible person contacts. Multiple responsible persons can be submitted in a single data exchange message.

CHALLENGES:

- A responsible person could be one of many different people who are stored within an EHR system: a parent, guardian, other next of kin, guarantor, caseworker, emergency contact, etc.
- The HL7 IG supports sending patient's next of kin, which might or might not also be the responsible person. IIS may treat all patient contacts submitted as a responsible person or may treat only the most recently submitted contact(s) as responsible.
- If responsible person does not have a corresponding code indicating relationship type, the data element's value is limited.
- **If missing:** It will not be available for patient matching. It could also be difficult to conduct reminder/recall activities where a responsible person contact for patients under age 19 is needed.
- **If inaccurate:** The opportunity to use this data element in patient matching and deduplication is limited. Inaccurate data in this field could result in a security violation if a patient history was inadvertently sent to the wrong responsible person or address.

EXPECTATIONS:

- IIS shall store the corresponding relationship-to-patient type code to responsible person name.
- IIS may derive mother's name from responsible person data where responsible person relationship type is mother.
- IIS shall not derive mother's maiden name from responsible person data where responsible person relationship type is mother.
- EHR systems shall submit responsible person name if known.
- EHR systems shall submit all responsible person data where relationship type is mother, father, or guardian. Data for relationship types of mother, father, or guardian take priority over other types, though other types may also be submitted.
- Vital Records systems shall submit responsible person type of mother if known.

EHR Systems

SHALL SUBMIT if known

Vital Records Systems

SHALL SUBMIT if known

IIS FUNCTIONAL STANDARD SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.

9.6 RESPONSIBLE PERSON RELATIONSHIP TO PATIENT



CDC DEFINITION: The actual personal relationship that the responsible person has to the patient.

Responsible person relationship to patient is intended to explain who the responsible person is and what their relationship to the patient is. The responsible person could be a parent (mother, father) or a guardian. It could also be a next of kin or a caseworker or guarantor.

CHALLENGES:

- A relationship to patient does not imply that the person is an appropriate contact or is primary caregiver. This may be the most challenging with regards to guardian, which is often a default relationship type, or for mother, which is often submitted regardless of that person’s role as a primary caregiver.
- If relationship to patient is noted as guardian, it is unclear what the true relationship to the patient is. A guardian could also be a mother, father, next of kin, caseworker, etc.
- Over time, the responsible person may change, and while some patients may still have a guardian or next of kin past of the age of 18, it would be unclear as to that person’s role. The utility of this data may also change over time as the patient ages.
- **If missing:** The value of responsible person data is limited in that the IIS does not know who the person is (relationship type) and what role they might play in the patient’s life. For example, a neighbor or grandparent might be submitted where the EHR has listed them as an emergency contact. That person should not be receiving outreach or reminders on behalf of the patient.
- **If inaccurate:** The opportunity to use in matching or patient outreach is limited.

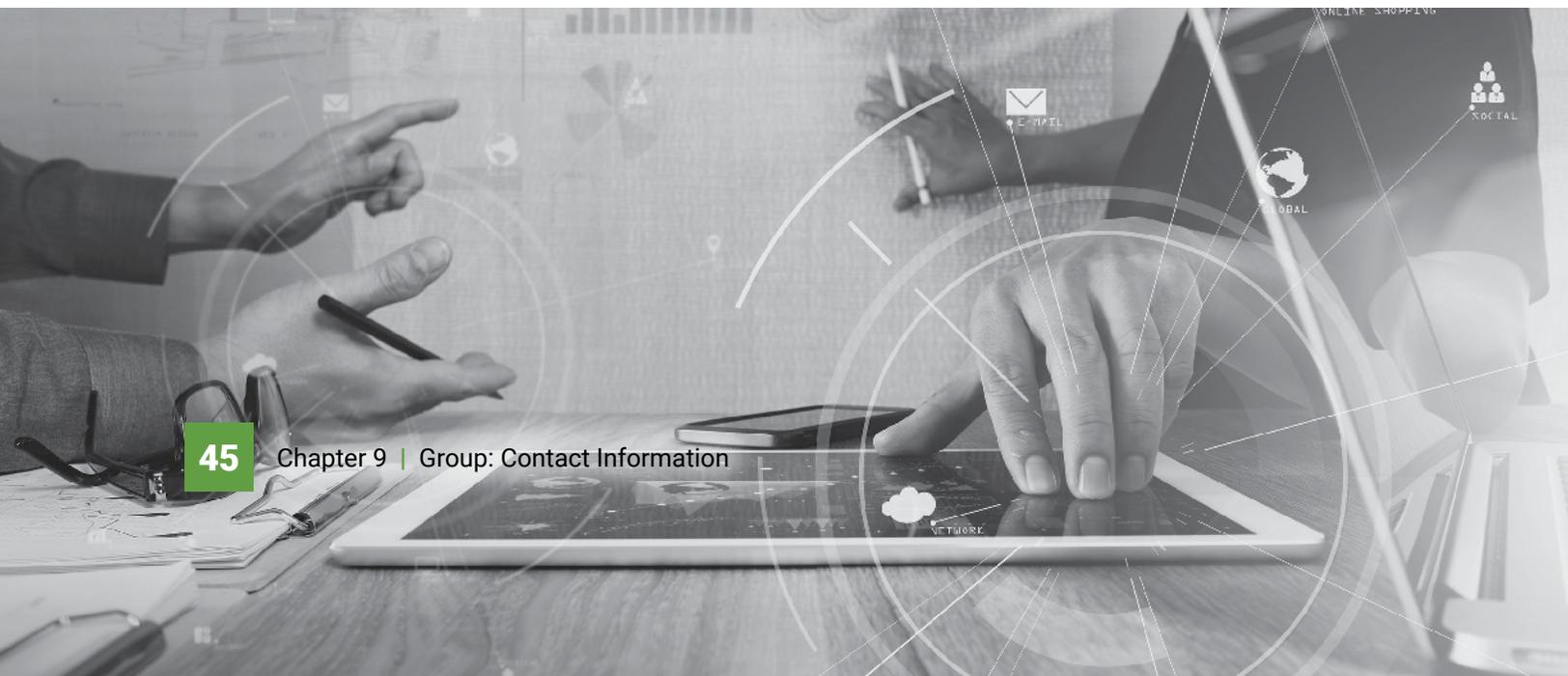
EXPECTATIONS:

- EHR systems shall submit responsible person relationship to patient whenever a responsible person is submitted.

IIS FUNCTIONAL STANDARD SUPPORTED:

- **2.0** The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.

EHR Systems
SHALL SUBMIT
Vital Records Systems
N/A





10

**GROUP: STATUS
/ PROTECTION**





10 STATUS / PROTECTION

10.1 PATIENT STATUS INDICATOR – JURISDICTION LEVEL



CDC DEFINITION: The patient/geographic jurisdiction status determined from address information when the patient's address within the jurisdiction is known. May be inferred as active at the jurisdiction level if the individual received an immunization from a provider organization within the jurisdiction.

The patient status indicator (jurisdiction level) is not submitted or entered by provider organizations. This data is generated within the IIS based on the patient's current address and immunization activity. Patients are considered "active" if they have a current address within the IIS geographic jurisdiction or have recently received an immunization within the IIS geographic jurisdiction and the address is unknown. Patients are considered inactive if they have an address outside the IIS geographic jurisdiction or are known to have died or left the jurisdiction. When active/inactive status is not maintained, either through automatic updates in the IIS or by manually updating those records, the IIS could have patients marked as active despite having an address outside the jurisdiction or being marked as deceased through a vital records update. See [MIROW Chapter on Management of Patient Active/Inactive Status in Immunization Information Systems](#).²⁰

Some IIS may manage patient status at more than one geographic jurisdiction level, such as county and state. Patients without an active status for any provider organization are often considered the responsibility of the designated jurisdiction, i.e., the geographic area covered by a local public health authority.

IIS may leverage patient status for data quality activities related to managing total IIS patient population. IIS may have business rules that support deduplication and management of patient records when patients move outside the jurisdiction or death records are received from Vital Records.

²⁰ <https://repository.immregistries.org/resource/management-of-patient-active-inactive-status-in-immunization-information-systems-1/>

CHALLENGES:

- Despite best efforts, patients can fall through the cracks and not have an active status with either a provider organization or at the jurisdiction level. The inverse is true as well. Patients might have an active status yet no longer live in the jurisdiction.
- IIS are not typically notified when patients move outside of the jurisdiction, making it difficult to manage an active patient population at the jurisdiction level. For IIS that manage patient status at the county level, this also becomes an issue if the patient moves out of the county but stays within the state-level jurisdiction.
- While some IIS receive death file notifications from the Vital Records system, updating those records is often a manual process, which is considered a challenge that takes time and resources to maintain.
- **If missing:** If patient status indicator (jurisdiction level) is missing, this could be interpreted as inactive, potentially leaving patients without a public health authority assessing their immunization status.
- **If inaccurate:** If patient status indicator (jurisdiction level) is inaccurate, it could affect the IIS’s ability to capture or assess data at the jurisdiction level, as the overall IIS patient denominator will be inflated. Patients with an inaccurate status of inactive could become lost to follow-up where there is neither a provider organization nor jurisdiction responsible. Patients who have moved out of the jurisdiction but are still marked active could affect reminder/recall activities.

EXPECTATIONS:

- IIS shall assign patient status at the jurisdiction level to ensure that patients within the jurisdiction are not inactivated at the jurisdiction level.

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **11.0** The IIS manages patient status at the provider organization and jurisdiction levels.
- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.
- **19.0** The IIS supports reminder and recall activities.

EHR Systems
N/A
Vital Records Systems
N/A

10.2 PATIENT STATUS INDICATOR – PROVIDER LEVEL



CDC DEFINITION: The current active/inactive status of the patient in relation to the provider organization.

The patient status indicator (provider level) supports a key function of the IIS: associating patient records to provider organizations through an active or inactive status. This association allows a provider organization to run reports and coverage assessments in the IIS based on its current (active) patient population. As patients move away, age out, or seek care elsewhere, provider organizations can manage their patient population in the IIS by marking those patients as inactive for their practice. Managing the patient active/inactive status assures accurate data for assessing up-to-date rates for current patients, estimating vaccine needs, and identifying patients for reminder/recall. Without managing patient status, the clinic’s rates in the IIS might not reflect its true patient population.

Patient status indicator (provider level) is specific to the provider organization. Patient status indicator (jurisdiction level) relates to the geographic area (e.g., county, state, etc.) associated with the patient. Many reports in the IIS support providers’ quality improvement activities, such as conducting reminder/recall or running coverage reports.

Typically, IIS will automatically create an association between a patient and a provider organization when a vaccination event is reported to the IIS. The rules for which type of provider organization (specific or all) can trigger this “active status” association vary from IIS to IIS. Local or IIS-specific rules may also vary regarding which types of vaccination events set an “active status” for a patient in the IIS. For further discussion on this topic, see [Management of Patient Active/Inactive Status in Immunization Information Systems](https://repository.immregistries.org/resource/management-of-patient-active-inactive-status-in-immunization-information-systems-1/).²¹

²¹ <https://repository.immregistries.org/resource/management-of-patient-active-inactive-status-in-immunization-information-systems-1/>

CHALLENGES:

- Provider organizations and IIS may define active and inactive patient status differently.
- Patient status is not easily updated to inactive via data exchange.
 - The IIS may have business rules that allow updates to patient demographics only if an administered vaccination event with a more recent date than any existing records occurs. (This is a fail-safe that prevents health plan and other non-immunizing data reporters from changing/reverting patient address to older data.)
 - The EHR may trigger HL7 messages to the IIS only when a vaccination event is recorded.
- Provider organizations and/or their EHRs may lack business rules or workflows for distinguishing patients who are no longer active with their clinic.
- Some IIS may be designed to support a one-to-one relationship between a patient and a provider organization, while other IIS may support a one-to-many relationship between a patient and provider organizations. This can be challenging for trading partners and provider organizations who must be aware where these relationship models differ.
- **If missing:** Patients might not be associated with any provider organization in IIS and might be lost to follow-up. Missing data might also impact clinic-based rates.
- **If inaccurate:** The numerators and denominators used to calculate coverage assessments will not be accurate. Clinic-based rates could be limited or inaccurate.

EXPECTATIONS:

- IIS shall support management of patient status through the user interface, via data exchange, and/or through IIS tools to globally (based on set parameters) update patient status by provider organization as a way to support organizations' quality improvement activities.
- EHR systems shall submit updates to patient demographics if known, such as a change of address where the patient has moved out of the jurisdiction as a means to updating active status.
- EHR systems shall submit patient status indicator (provider level) if known.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **11.0** The IIS manages patient status at the provider organization and jurisdiction levels.
- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.



10.3 PROTECTION INDICATOR



CDC DEFINITION: This element identifies whether a person's information may be shared with others, as defined locally (e.g., opt out).

The protection indicator flag is used to indicate if a patient's immunization history may be shared with other providers. The protection indicator does not indicate whether data should be sent to the IIS; rather, it indicates how that data should be treated once it is in the IIS.

Local laws and policy guide how IIS can share (or not share) patient immunization history when patients have indicated they would like their data protected from viewing by other providers. These policies are typically referred to as opt-in or opt-out policies. There are variations on the two concepts; an IIS that operates with an opt-in policy requires that patients give explicit permission for sharing their immunization history with other providers. If an IIS operates with an opt-out policy, it means patients must proactively indicate that they do not want their immunization history shared with other providers. IIS must determine the optimal way to manage queries for patients with records indicated as not for sharing; the IIS may choose to send either a "not found" or something more explicit indicating the record cannot be shared. Similarly, if a search for a patient record is done on the IIS user interface, an appropriate message on screen should indicate that the record cannot be shared or was not found.

There is another way in which the protection indicator is sometimes utilized. This is where the IIS uses the protection indicator to record patients' consent to submit their data to the IIS. While this is not the standard usage for the protection indicator, it may be appropriate based on local IIS policy.

CHALLENGES:

- Policies across jurisdictions vary in how they are written and/or how they are implemented. This can prove difficult for EHRs to support if it means making custom changes to their interfaces.
- Sometimes the protection indicator is interpreted to mean that data should not be sent from the EHR to the IIS. That is not the intent of the protection indicator, which indicates how the IIS should treat patient data once it is in the IIS: share with other providers or don't share with other providers. This should not be confused with policies that some jurisdictions have requiring consent from the patient to send data to the IIS.
- With the release of the HL7 IG, the definition for protection indicator was corrected to align with the HL7 definition. The meaning of the protection indicator is dependent on the base version of the HL7 used by a given message. This change created the need for explicit discussion and agreement between EHRs and IIS during onboarding or while troubleshooting suspected data issues.
- **If missing:** If protection indicator is missing, how the data is shared (or not) will be guided by local IIS policy.
- **If inaccurate:** If protection indicator is inaccurate, the opportunity to share/update a consolidated patient record with an external partner could be missed. Alternatively, sharing of patient data might occur without that patient's explicit permission, which could be considered a security violation.

EXPECTATIONS:

- IIS shall support provider organizations by providing clear documentation on how sharing and protection of data work within the IIS.
- EHR systems shall submit protection indicator if known and in conjunction with local policy on sharing records.
- EHR systems shall not utilize protection indicator to filter patient records from sending to the IIS unless otherwise requested by the IIS.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARD SUPPORTED:

- **4.0** The IIS implements written and approved confidentiality policies that protect the privacy of individuals whose data are contained in the system.

10.4 PROTECTION INDICATOR EFFECTIVE DATE



CDC DEFINITION: The effective date for the protection indicator.

The **protection indicator** flag is used to indicate if a patient's immunization history may be shared with other providers. The protection indicator effective date indicates when the current (or incoming) protection indicator became effective.

The protection indicator for a patient will update based on business rules established by the IIS. The protection indicator effective date is leveraged to determine the most recent patient wishes regarding sharing immunization history.

CHALLENGES:

- In jurisdictions where the protection indicator (and effective date) are required for submission to the IIS, this could pose a challenge for EHRs that do not require this field to be entered.
- **If missing:** If protection indicator effective date is missing in an incoming message, the protection indicator might be ignored.
- **If inaccurate:** If protection indicator effective date is inaccurate, there is a risk that patient data might be shared (or not shared) with other provider organizations without the approval of the patient.

EXPECTATIONS:

- IIS shall utilize protection indicator effective date as needed in managing patient history sharing settings.
- EHR systems shall submit protection indicator effective date in conjunction with protection indicator if known.

IIS FUNCTIONAL STANDARD SUPPORTED:

- **4.0** The IIS implements written and approved confidentiality policies that protect the privacy of individuals whose data are contained in the system.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A



11

**GROUP:
VACCINATION**



11 VACCINATION



11.1 VACCINE PRODUCT



CDC DEFINITION: The vaccine type that may be administered, historical, or refused, and is messaged using the NDC or CVX code sets.

Vaccine product is the term representing a specific vaccine type, such as MMR. It is communicated between an external system (e.g., EHR) and the IIS using national coding systems such as CVX (vaccine product administered) or National Drug Code (NDC). IIS may (or may not) store vaccine product as CVX or NDC. An internal representation may be used and cross-walked to a national coding system.

Vaccine product populates the patient's immunization history and forecast and is the basis for many reports on queries such as doses administered, inventory management, and ordering.

When paired with vaccine manufacturer, CVX can be cross-walked to a trade name. A single vaccine product may cross-walk to multiple trade names; the manufacturer makes it explicit. When vaccine product is represented as an NDC code, cross-walking is unnecessary, as the detail is embedded in the code.

Based on local need, vaccine product may include immunoglobulin.

NDC codes, specifically, were identified in regulations in Centers for Medicare and Medicaid Services (CMS) incentive programs as the preferred vaccine code set for EHR system submission of administered doses to IIS.

CHALLENGES:

- Maintaining vaccine product tables and cross-walks in the IIS and in the EHR is a time-consuming and resource-intensive effort. As new vaccine products come on the market, new codes must be added to the IIS as quickly as possible to ensure that data will be accepted when doses are reported to the IIS. The same challenge applies to EHRs and other sending systems: all parties must maintain accurate and up-to-date vaccine code sets. As CDC finds new ways to present and share vaccine code sets and cross-walking tables and tools, the IIS and EHR communities should find some relief in what is currently accomplished through mostly manual updates.
- **If missing:** If vaccine product is missing in the IIS, doses reported by data exchange will be rejected. This can result in patient records not being up to date, and it can affect inventory management.
- **If inaccurate:** If vaccine product is inaccurate, the patient record will not be updated correctly, and it could result in the patient being over- or under-immunized. It could affect forecasting, causing patients to show due or complete when they are not, and it could affect practice-level coverage rates and reminder/recall.

EXPECTATIONS:

- IIS shall support CVX and NDC as vaccine codes used for submitting vaccination event details and for inventory management tasks. Usage of CPT codes should be limited.
- EHR systems shall maintain vaccine product tables.
- EHR systems shall submit unspecified CVX codes for historical doses only.
- EHR systems shall submit vaccine product.
- Vital Records systems shall submit vaccine product if known.

EHR Systems
SHALL SUBMIT
Vital Records Systems
SHALL SUBMIT if known

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.
- **10.0** The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.
- **12.0** The IIS supports vaccine product recall activities.
- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **25.0** The IIS supports provider-site level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.



11.2 VACCINATION EVENT RECORD TYPE



CDC DEFINITION: Indicates whether the vaccination event is based on a historical record or was given by the administered-at-location.

Vaccination event record type is key to maintaining a consolidated patient vaccination record of all vaccination events over a patient's lifetime.

The vaccination event record type indicates if the vaccine was administered by a provider at the reporting clinic (administered) or if it was given elsewhere (historical). This is an important concept in both IIS and EHRs, as different business rules and processing are applied depending on how the dose is coded. Doses marked as administered must typically meet stricter data quality standards than doses marked as historical.

During vaccination deduplication, the vaccination event record type code is used to determine if the incoming vaccination record is "better" than a matching existing vaccination record. Generally, a vaccination event marked as administered will overwrite an existing (and matching) vaccination event marked as historical. For more detail on IIS business rules for consolidating records, see the [MIROW Guide: Consolidating Demographic Records and Vaccination Event Records](https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/).²²

²² <https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/>

The vaccination event record type, if indicated as administered, should trigger the inventory deduction process in IIS that have inventory management functionality. Additional business rules in the IIS may need to be met in order for the inventory deduction process to be completed, such as how recent is the administration, is the provider organization set up for inventory deduction, and has the incoming dose been previously deducted.

IIS leverage vaccination event record type to assess data quality. Monitoring for expected volumes of administered to historical doses submitted can indicate a problem with data entry or the interface. Depending on the type of sending organization (provider organization, health plan, pharmacy, non-immunizing reporter such as school, etc.), expectations for percentage of administered to historical vaccination event reports will vary. In some cases, such as health plans or schools, the IIS will expect only historical vaccination events to be reported.

The HL7 IG supports nine values for sending vaccination event record type.²³ Most frequently, only two record types are used (administered and historical), though some IIS local guidance may request or encourage the usage of additional codes expanding the granularity of “historical.” Such expanded concepts include “from other registry,” “from written record,” and “from other provider” among others.

CHALLENGES:

- Provider organizations or EHRs might misinterpret the code for a historical dose as indicating older data rather than “given elsewhere.” Historical indicates that the reporting provider did not administer the dose.
- A backload of data that includes doses marked as administered might inadvertently affect inventory.
- **If missing:** The incoming dose would be presumed to be historical. IIS functions such as inventory and vaccine accountability would not be able to be leveraged, potentially resulting in issues or errors with vaccine management.
- **If inaccurate:** Forecasting could be affected. Doses marked inaccurately as administered can create duplicate vaccination events or inadvertently overwrite historical doses incorrectly. Issue or errors with vaccine management could occur.

²³ <https://repository.immregistries.org/resource/hl7-version-2-5-1-implementation-guide-for-immunization-messaging-release-1-5-1/>

EXPECTATIONS:

- IIS shall store historical doses from provider organization and other reporting/sending organizations. Capturing historical doses in the IIS fills gaps in patient records. This is increasingly important for creating consolidated vaccination records across the lifespan.
- EHR systems shall submit doses administered by the provider organization with the administered code, regardless of date of administration.
- EHR systems shall submit doses not administered by the provider organization with an appropriate historical code.
- EHR systems shall have the ability to submit historical data to an IIS. As historical vaccination events are entered into the EHR as part of a patient visit or intake for new patients, those vaccination events shall be submitted to the IIS.
- EHR systems should submit a backload of data, on behalf of the provider organization as an onboarding activity, EHR migration, or resolution of missing data. This should be closely coordinated with the IIS team to ensure that backloaded data does not inadvertently trigger inventory deduction or cause other unintended data quality issues.
- Vital Records systems (and other secondary source data systems) should submit vaccination event record type as historical for all vaccination events reported.

EHR Systems
SHALL SUBMIT
Vital Records Systems
SHALL SUBMIT

IIS FUNCTIONAL STANDARD SUPPORTED:

- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.

11.3 VACCINE MANUFACTURER NAME



CDC DEFINITION: The manufacturer of the vaccine that was administered.

Vaccine manufacturer name²⁴ provides an opportunity for capturing further details on an administered vaccine. In addition to supporting the details of a patient immunization history, vaccine manufacturer name is used in the IIS to support vaccine management functions such as inventory, ordering, and accountability reporting. Provider organizations that participate in the Vaccines for Children program or other, state-supplied vaccine programs may use these vaccine management functions in the IIS to support their day-to-day work.

Vaccine manufacturer name may display in IIS reports along with manufacturer code. The manufacturer code, or MVX, is the value that is exchanged through electronic data exchange. The CDC owns and maintains the [manufacturer code set](#).²⁵ The CDC code set, [Mapping product Names to CVX and MVX](#),²⁶ provides the active/inactive status on current and past manufacturers of specific vaccine products.

Vaccine manufacturer information (name and code) are used in IIS reports that present information about vaccines administered, inventory used and remaining, and ordering vaccines. Vaccine manufacturer information, code specifically, may be used by IIS as part of data quality checks, either routine or during onboarding. If the vaccine code (CVX or NDC) and the MVX code reported on the same vaccination administration event do not match, it could signal a data quality issue.

²⁴ Vaccine manufacturer name is the CDC endorsed data element. For the purposes of this guide, discussion in this section will cover both manufacturer name and code.

²⁵ <https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=mvx>

²⁶ <https://www2a.cdc.gov/vaccines/iis/iisstandards/vaccines.asp?rpt=tradename>

CHALLENGES:

- As manufacturer acquisitions take place, vaccine products may come under new or different manufacturers. Determining which manufacturer to send (the labeler or actual manufacturer) can prove confusing to provider organizations managing inventory and ordering in the IIS.
- Similarly, a vaccine product may be ordered through one company but manufactured (and labeled) by a subsidiary company. This can cause further confusion about which manufacturer should be reported to an IIS.
- **If missing:** If vaccine manufacturer name is missing in the IIS, it could affect the display of a vaccine product name on the patient history. It can also limit evaluation and forecasting when an ACIP recommendation is trade-name specific, and the patient would be forced onto a more generic schedule. Additionally, the opportunity to validate against the incoming vaccine code during data exchange is missed.
- **If inaccurate:** If vaccine manufacturer name is inaccurate, causing a mismatch between vaccine code and MVX, it could cause the incoming data to be rejected if the IIS requires validation of both codes.

EXPECTATIONS:

- IIS shall maintain up-to-date code sets for manufacturer.
- EHR systems shall maintain up-to-date code sets for manufacturer.
- EHR systems shall submit manufacturer for all vaccination events reported to the IIS as administered.

EHR Systems
SHALL SUBMIT
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **8.0** The IIS exchanges data with health information systems in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.
- **10.0** The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.
- **12.0** The IIS supports vaccine product recall activities.
- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **25.0** The IIS supports provider-site level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.

11.4 VACCINE LOT NUMBER



CDC DEFINITION: The lot number of the vaccine administered.

Vaccine lot number supports many functions in the IIS, such as maintaining a consolidated immunization record, conducting vaccine recalls, vaccine usage reporting, and inventory management.

The vaccine lot number is used to decrement inventory as doses are reported as administered through electronic data exchange. Inventory management functionality in the IIS is organized around lot number, doses are added, transferred in/out, and deducted based on the lot number and additional required fields, such as CVX and vaccine funding source.

CHALLENGES:

- Hand-keyed lot numbers result in numerous and unnecessary data entry errors. When the lot number sent by the EHR does not match the lot number in the IIS, inventory deduction may fail, and vaccine accountability is affected.
- Provider organizations sometimes prepend or append extra characters to lot numbers for the purposes of categorizing inventory between public and private stock. Doing this can cause mismatch between the lot number reported and the lot in the IIS, causing inventory deduction to fail.
- Some vaccine products are listed with two different lot numbers, one on the unit of use and one on the unit of sale. The unit of sale lot number is what will be recorded in the provider organization's inventory for publicly purchased vaccine as that data is populated from the CDC's vaccine management system called **VTrcks**.²⁷ Recording the unit-of-sale lot number at the point of administration is challenging, as the clinician might not have the outer packaging in hand. See [Guidance on Unit of Sale/Unit of Use Lot Numbers](#)²⁸ and [Validating Lot Numbers for Vaccine Doses](#).²⁹

²⁷ <https://www.cdc.gov/vaccines/programs/vtrcks/index.html>

²⁸ [Guidance on Unit of Sale/Unit of Use Lot Numbers](#)

²⁹ <https://repository.immregistries.org/resource/mirow-micro-guide-lot-number-validation-best-practices/>

- Lot numbers for certain reconstituted vaccines will differ for the unit of use and unit of sale. See [Guidance on Unit of Sale/Unit of Use Lot Numbers](#).³⁰
- **If missing:** Inventory deduction will likely fail, and it might affect vaccine product recall, where patients that had received the lot would not be able to be identified.
- **If inaccurate:** The wrong inventory might be deducted or might fail to deduct. It could also indicate a data entry error or a clinical error. Additionally, if there is a vaccine recall, the lot number would be used to identify patients needing revaccination or follow-up. Incorrect information could have clinical implications for the patient.

EXPECTATIONS:

- IIS shall store either unit-of-use lot number or unit-of-sale lot number.
- EHR systems shall submit lot number for all vaccination events reported to the IIS as administered. Lot number is not expected when the vaccination event is reported as historical.
- EHR systems shall submit lot numbers as indicated on the vial (unit of use) or the box (unit of sale), and lot numbers shall not be pre-fixed or appended with numbers or characters by the provider organization.

EHR Systems
SHALL SUBMIT
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.
- **12.0** The IIS supports vaccine product recall activities.
- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **14.0** The IIS supports public health response during disease outbreaks.
- **25.0** The IIS supports provider-site level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.

³⁰ <https://repository.immregistries.org/resource/guidance-on-unit-of-sale-unit-of-use-lot-numbers/>

11.5 VACCINE ROUTE OF ADMINISTRATION



CDC DEFINITION: The route of administration.

Vaccine route of administration describes the method of administration, such as intramuscular, intranasal, or oral.

Route and site are often paired together in reports to describe how and where the vaccine was administered. Route and site may be useful during Vaccine Adverse Event Reporting Systems (VAERS) investigations and during vaccine recall activities. While IIS data can be used to support outreach and investigations, the EHR is considered the official medical record for patients.

CHALLENGES:

- If route and site are unrelated data elements in the EHR, unexpected combinations might be submitted. Without follow-up to the provider organization, the IIS cannot determine if these are clinical errors or data entry errors, e.g., a dose is submitted as administered with a route of intramuscular and a site of left nares.
- **If missing:** The IIS would be unable to validate the accuracy of administration. In scenarios where the IIS is considered the primary vaccination event record, such as during outbreaks or a mass vaccination event, route and site are required.
- **If inaccurate:** A data entry error or a clinical error might be indicated. In limited and rare scenarios, ACIP requires a certain vaccine to be administered or prevented from being administered in a specific route and site.

EXPECTATIONS:

- IIS shall store vaccine route of administration when submitted.
- EHR systems shall submit route of administration if known.

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **19.0** The IIS supports reminder and recall activities.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

11.6 VACCINE SITE OF ADMINISTRATION



CDC DEFINITION: The anatomical site where the vaccine was given.

Vaccine site of administration is the anatomical location where the vaccine was administered.

Route and site are often paired together in reports to describe how and where the vaccine was administered. Route and site may be useful during VAERS investigations and during vaccine recall activities. While IIS data can be used to support outreach and investigations, the EHR is considered the official medical record for patients.

CHALLENGES:

- If route and site are unrelated data elements in the EHR, unexpected combinations may be submitted. Without follow-up to the provider organization, the IIS cannot determine if these are clinical errors or data entry errors, e.g., a dose is submitted as administered with a route of intramuscular and a site of left nares.
- **If missing:** The IIS would be unable to validate the accuracy of administration. In scenarios where the IIS is considered the primary vaccination event record, such as during outbreaks or a mass vaccination event, route and site are required.
- **If inaccurate:** A data entry error or a clinical error might be indicated. In limited and rare scenarios, ACIP requires a certain vaccine to be administered or prevented from being administered in a specific route and site.

EXPECTATIONS:

- IIS shall store vaccine site of administration when submitted for administered doses.
- EHR systems shall submit site of administration if known.

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **19.0** The IIS supports reminder and recall activities.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

11.7 DOSE LEVEL ELIGIBILITY



CDC DEFINITION: The program that should pay for a given immunization, based on the characteristics of the patient and the type of vaccine administered. Eligibility is captured per dose.

Participation in the Vaccines for Children or other, state-supplied vaccine programs requires accountability for each dose of vaccine administered. This is often accomplished through submission of a dose-level eligibility code via data exchange or when adding immunizations via the IIS user interface.

Dose-level eligibility describes the reason the patient is eligible to receive no-cost vaccine provided through the Vaccines for Children program or other, state-supplied vaccine programs. For example, a patient under 19 years of age who has Medicaid is eligible to receive no-cost VFC vaccine.

The immunization program will use this data to ensure that participating provider organizations are accountable for all federally or state-supplied vaccine. Additionally, IIS and providers may use this data to inform future vaccine needs and ordering activities. Dose-level eligibility may also be used in IIS to support other processes during data exchange, such as decrementing inventory. IIS teams may work closely with program managers and VFC managers to ensure that requirements for eligibility coding and data submission are clear and shared with provider organization partners as well as EHR partners.

It is important to note that, depending on the vaccine supply model implemented by an immunization program, dose-level eligibility may be managed differently. States with a universal vaccine supply model may have different dose-level coding requirements from states that operate as VFC-only.^{31,32}

³¹ <https://www.cdc.gov/vaccines/programs/vfc/providers/eligibility.html>

³² <https://www.cdc.gov/vaccines/programs/vfc/about/vac-supply-policy/supply-2009.html>

CHALLENGES:

- In addition to the standard five eligibility categories, which apply to patients younger than 19 years old, there are four additional categories, which cover state program eligibility, CHIP, 317, and Medicare. Additionally, some immunization programs may have a need for additional state-specific eligibility codes. While this is supported in the HL7 IG, it does mean that the EHR must be able to configure state-specific eligibility codes.
- Requirements for which doses and patients should be accounted for with eligibility codes may differ from one jurisdiction to the next depending on how they operate their VFC program. This can prove challenging to an EHR or other type of submitting system if it requires customization to the local interface, such as programs that require all patients' doses be coded for eligibility, including adult patients.
- Not all clinics in a particular jurisdiction participate in the VFC program. Therefore, EHRs cannot easily make the capture of eligibility codes in the EHR a required field, as it would not serve all customers.
- **If missing:** The responsible organization is at risk for not being accountable for vaccine funded through the VFC or other, state-supplied vaccine programs.
- **If inaccurate:** Doses could be accounted for under the incorrect eligibility category.

EXPECTATIONS:

- EHR systems shall support provider organizations' submission of dose-level eligibility for all administered doses to meet accountability and participation requirements in the VFC program or any state-supplied vaccine program.
- EHR systems shall have the ability to add, update, or delete jurisdiction-specific eligibility codes to support state-funded vaccine programs.
- EHR systems shall submit dose level eligibility for administered doses where the provider organization participates in the VFC program and/or receives state-supplied vaccine.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARD SUPPORTED:

- **25.0** The IIS supports provider-site level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.

11.8 VACCINE FUNDING SOURCE



CDC DEFINITION: The funding source of the vaccine administered. That is, was the vaccine administered purchased as publicly funded, privately funded, or with other jurisdiction-specific funding.

Vaccine funding source describes how the administered vaccine was purchased or “funded.” Provider organizations participating in the Vaccines for Children program or receiving other, state-supplied vaccine may be required to submit the vaccine funding source along with the dose-level eligibility code for each administered dose.

The vaccine funding source indicates if public or private vaccine stock was administered and, if public, which stock if more than one exists, such as VFC, 317, or state-supplied.

Some IIS may leverage vaccine funding source as part of the inventory management and decrementing process. Vaccine funding source may also be leveraged in IIS reports that support provider organizations’ reporting and accountability for VFC, 317, and state-supplied vaccine.



CHALLENGES:

- If submission requirements vary from one IIS jurisdiction to another, that can pose a challenge to EHRs if that means changing or configuring customizations to the interface.
- **If missing:** The provider organization might not be able to fully account for doses administered to patients eligible for federally or state-supplied vaccine. Additionally, it would limit the ability of a provider organization to estimate vaccine needs for future years.
- **If inaccurate:** There might be errors in the provider organization’s accountability for federally or state-supplied vaccine.

EXPECTATIONS:

- IIS shall store vaccine funding source if required for provider organizations participating in the Vaccines for Children or other, state-supplied vaccine programs.
- IIS should ignore vaccine funding source if it is not required locally.
- EHR systems should have the ability to submit vaccine funding source.
- EHR systems shall submit vaccine funding source on administered doses if required for provider organizations participating in the VFC or other, state-supplied vaccine programs.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **25.0** The IIS supports provider-site level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.



11.9 VACCINE INFORMATION STATEMENT



CDC DEFINITION: The publication date of the vaccine information statement expected to be captured in the IIS if the IIS is used as the primary vaccination event record (e.g., mass vaccination clinic).

Vaccine information statements (VIS) inform patients about the specific benefits and risks of the vaccine they are receiving. VIS are provided to patients to fulfill the requirements of the [National Childhood Vaccine Injury Act \(NCVIA\)](#).³³ All vaccine providers, public or private, are required by the National Childhood Vaccine Injury Act to give the appropriate VIS to the patient (or parent or legal representative) prior to every dose of specific vaccines.³⁴ Part of the requirements under the NCVIA is that the provider must record specific information in the patient's medical record or in a permanent office log.³⁵ While all providers (public or private) of vaccines are required to provide VIS to their patients, VFC providers have the added responsibility to demonstrate that they are following these requirements by providing evidence that the VIS and VIS given date are recorded in the patient's clinical record. This is typically verified during a VFC site visit.

The VIS (and related VIS given date) need to be recorded in the IIS only when the IIS is considered the primary vaccination event record (e.g., mass vaccination event). The usage of VIS is thus limited to specific scenarios and events. For the purposes of this guide, a primary vaccination event record is the official record of the vaccination event recorded by the provider organization, in an EHR, by the IIS, or on paper.

³³ <https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapXIX-part2-subpartc-sec300aa-26.pdf>

³⁴ <https://www.cdc.gov/vaccines/hcp/vis/about/facts-vis.html>

³⁵ <https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapXIX-part2-subpartc-sec300aa-26.pdf>

CHALLENGES:

- There is limited utility for this data in the IIS. It could be mistaken as a requirement for submission with all administered doses all of the time because of the strict requirements that VIS be provided to patients and that VFC providers must prove adherence to these requirements.
- The 2015 CEHRT³⁶ (certified EHR technology) tests whether EHRs can send VIS for all administered doses. Because this is tested in the certification process and noted in the HL7 IG as required, it is not unusual for EHRs to assume that VIS shall be sent for all administered doses to the IIS. IIS onboarding teams spend significant time explaining the scenarios under which sending VIS would apply.
- This data element has a low value to high complexity ratio for IIS, as evidenced in the testing and assessment work accomplished through AIRA's Measurement and Improvement Initiative.³⁷ Data from AART (Aggregate Analysis Reporting Tool) shows frequent nonstandard handling of VIS data in HL7 messaging by IIS, which impacts IIS test results.
- Local policy may affect if/when/how an IIS can be considered or used as a primary vaccination event record or as a clinical record for a patient.
- Under scenarios where it is appropriate to send the VIS to the IIS, the HL7 IG indicates two methods for submission. The preferred method involves the provider's scanning the VIS barcode into an EHR using a bar code reader and acceptance of the bar code Global Trade Item Number (GTIN) by the IIS. Updating IIS functionality to accept bar codes via HL7 messaging could be a challenge where other enhancements have greater priority. The second method for submission is retained in the HL7 IG to support backward compatibility. This method is accomplished through submission of three HL7 OBX segments to indicate vaccine type, VIS publication date, and VIS given date.
- **If missing:** A missing VIS (when the IIS is considered the primary vaccination event record) could indicate that the provider is not documenting that the VIS was given to the patient. It could also indicate a workflow issue, such as when the VIS is provided to the patient prior to the appointment. Despite these issues, missing VIS will likely not have a negative impact on the IIS.
- **If inaccurate:** A mismatched VIS to administered vaccine may indicate a data quality issue or that the incorrect VIS was provided to the patient.

³⁶ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html>

³⁷ <https://www.immregistries.org/measurement-improvement>

EXPECTATIONS:

- IIS shall store VIS *only under circumstances* where the IIS is considered the primary vaccination event record. When the VIS is not meeting that need, IIS shall ignore the VIS data sent with administered doses and not return warnings or errors in acknowledgments for issues on data not utilized and/or stored.
- The administering provider shall record the VIS directly in the IIS if it is considered the primary vaccination event record.

EHR Systems
N/A
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **8.0** The IIS exchanges data with health information systems in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.

11.10 VACCINE INFORMATION STATEMENT GIVEN DATE



CDC DEFINITION: The date the VIS was provided to the patient and expected to be captured in the IIS if the IIS is used as the primary vaccination event record (e.g., mass vaccination clinic).

Vaccine information statements inform patients about the specific benefits and risks of the vaccine they are receiving. VIS are provided to patients to fulfill the information requirements of the [National Childhood Vaccine Injury Act \(NCVIA\)](#).³⁸ For more detail see the section on [vaccine information statement](#). The vaccine information statement given date is specifically the date that the provider gave the VIS to the patient. Typically, this would be the same date as administration date, though sometimes it is provided in advance of the appointment.

³⁸ <https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/pdf/USCODE-2010-title42-chap6A-subchapXIX-part2-subpartc-sec300aa-26.pdf>

CHALLENGES:

Note: The challenges mirror what is stated for vaccine information statement, as this data element supports the previously described data element, Vaccine Information Statement.

- There is limited utility for this data in the IIS. It could be mistaken as a requirement for submission with all administered doses all of the time because of the strict requirements that VIS be provided to patients and that VFC providers must prove adherence to these requirements.
- The 2015 CEHRT³⁹ (certified EHR technology) tests whether EHRs can send VIS for all administered doses. Because this is tested in the certification process and noted in the HL7 IG as required, it is not unusual for EHRs to assume that VIS shall be sent for all administered doses to the IIS. IIS onboarding teams spend significant time explaining the scenarios under which sending VIS would apply.
- This data element has a low value to high complexity ratio for IIS, as evidenced in the testing and assessment work accomplished through AIRA's Measurement and Improvement Initiative.⁴⁰ Data from AART (Aggregate Analysis Reporting Tool) shows frequent nonstandard handling of VIS data in HL7 messaging by IIS, which impacts IIS test results.
- Local policy may affect if/when/how an IIS can be considered or used as a primary vaccination event record or as a clinical record for a patient.
- Under scenarios where it is appropriate to send the VIS to the IIS, the HL7 IG indicates two methods for submission. The preferred method involves the provider's scanning the VIS barcode into an EHR using a bar code reader and acceptance of the bar code GTIN by the IIS. Updating IIS functionality to accept bar codes via HL7 messaging could be a challenge where other enhancements have greater priority. The second method for submission is retained in the HL7 IG to support backward compatibility. This method is accomplished through submission of three HL7 OBX segments to indicate vaccine type, VIS publication date, and VIS given date.
- **If missing:** It would be unclear as to if or when the VIS was provided to the patient. With regards to HL7 data exchange, the VIS given date must accompany the VIS in the message per the HL7 IG.
- **If inaccurate:** It could misrepresent what actually happened, or it could indicate a data quality issue, such as when the publication date is sent, instead of the given date.

³⁹ <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Certification.html>

⁴⁰ <https://www.immregistries.org/measurement-improvement>

EXPECTATIONS:

- IIS shall store VIS given date *only under circumstances* where the IIS is considered the primary vaccination event record. When the VIS is not meeting that need, IIS shall gracefully ignore the VIS data sent with administered doses.
- EHRs shall submit VIS given date *only under circumstances* where the IIS is considered the primary vaccination event record.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **8.0** The IIS exchanges data with health information systems in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.
- **26.0** The IIS provides data or produces reports for VFC and state and local immunization programs.



11.11 CONTRAINDICATIONS/PRECAUTIONS



CDC DEFINITION: A reason(s) to consider not giving a patient a vaccine proposed for administration.

A provider may report contraindications or precautions for a specific patient. These contraindications may be independent of a vaccination event or specific to a vaccination event. That information is saved to the patient record in the IIS and may be leveraged for clinical decision support.

Contraindications (conditions in a recipient that increase the risk for a serious adverse reaction) and precautions to vaccination are conditions under which vaccines should not be administered.⁴¹ The patient may be at risk for a serious adverse event if the vaccination is administered, e.g., the patient is allergic to eggs.

An underlying condition (such as pregnancy) can sometimes be considered both a contraindication for vaccinations and an indication for vaccinations.

If patients have a contraindication to a specific vaccine, they may receive a medical exemption from their provider for documentation related to school (or childcare, camp) attendance. Refusals for non-medical reasons are not contraindications.

A precaution is a condition in a recipient that might increase the risk for a serious adverse reaction, might cause diagnostic confusion, or might compromise the ability of the vaccine to produce immunity (e.g., administering measles vaccine to a person with passive immunity to measles from a blood transfusion administered up to seven months prior).⁴²

Contraindications and precautions may reflect temporary or permanent conditions and are typically reported with an accompanying observation date. Some contraindications (such as pregnancy) are time sensitive, while others may indicate a lifelong condition, such as chronic disease or allergy.

⁴¹ <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>

⁴² <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>

Clinical decision support tools will typically take contraindications into consideration when forecasting immunizations due next for a patient.

Medical exemptions are a related concept to contraindications. A medical exemption, typically used to meet school or childcare requirements, is formal documentation from a provider that the patient does not need to receive an immunization for specific medical reasons. Children with a medical exemption for a specific vaccine would be exempt from that school requirement.

CHALLENGES:

- If no vaccinations were administered during the patient visit, a triggering event would need to occur for the contraindication to be sent to the IIS from the EHR. Not all EHRs support sending messages when there isn't a vaccination event (administered or historical) to report, and not all IIS support receiving messages without vaccination events and only contraindications.
- Pregnancy is an example of a contraindication that is also considered an indication. It is an indication for Tdap and a contraindication for any live vaccine. At this time in the HL7 IG, pregnancy is messaged as a contraindication.
- Some contraindications may be vaccine-product specific while other products in the same family could still be administered.
- Some contraindications are temporary and will require also sending a date indicating the end of the contraindication.
- **If missing:** Doses might be administered that are actually contraindicated.
- **If inaccurate:** Doses might be administered that are actually contraindicated, or a missed opportunity to immunize could occur. It would also affect forecasting.

EXPECTATIONS:

- IIS shall store contraindications if received.
- IIS shall store precautions if there is intent to use the information provided.
- IIS shall utilize information about contraindications as part of clinical decision support.
- IIS shall send contraindications and precautions in a query response. This allows the next provider to see the patient's complete information.
- EHR systems should submit contraindications and precautions if known.

EHR Systems
SHOULD SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

- **10.0** The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.
- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **18.0** The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.
- **19.0** The IIS supports reminder and recall activities.

11.12 EXEMPTIONS/REFUSALS REASON



CDC DEFINITION: The reason for an exemption or refusal.⁴³

Exemptions/Refusals Reason describes the reason the patient refused the vaccine, such as patient decision, parental decision, or religious- or philosophical-based refusal.

When a patient refuses a vaccination, it may be helpful to capture the reason. This information may be useful to the provider that sees the patient next.

When a patient refuses a vaccination, the provider may record that refusal in the EHR. In this scenario, if supported, the EHR can send information that the vaccination was refused and why. The IIS captures this information on the patient record. A date, as well as the specific vaccine refused, are recorded.

Note: If a patient is contraindicated for a vaccine, the concept of refusal does not apply. Contraindications should not be recorded as refusals in the EHR or the IIS. If this patient in this scenario attends a school or childcare (or workplace) that requires vaccines, the provider may provide a medical exemption as documentation for why the dose was not administered.

⁴³ It is anticipated that in the next update to the CDC endorsed data elements, Exemptions/Refusals Reason will be separated into two distinct data elements as exemptions and refusals. These concepts are distinctly different, and for the purposes of this Functional Guide, the definition and usage details focus on the concept of refusal.

CHALLENGES:

- Refusals sent via HL7 messaging are formatted very similarly to administered doses and, without careful attention, can be easily mistaken for administered doses. As such it is important that both EHRs and IIS thoroughly test to ensure that these refused doses are processed correctly.
- Providers might not record refusals in the EHR, or refusals might not be captured in the EHR as actionable data. EHRs might not have the ability to trigger a message to the IIS when a vaccination event has not been recorded.
- Recording a refusal of a vaccine does not circumvent the need for a patient to get vaccinated. It simply states that the patient did not receive a vaccine. Most importantly, the patient is still considered unprotected, and follow-up is appropriate.
- Not all jurisdictions accept the same set of refusal or exemption reasons. Policy varies from one jurisdiction to the next.
- **If missing:** The incoming data indicating the vaccination was refused will likely be rejected, as the refusal reason is required.
- **If inaccurate:** A refusal might be recorded on the patient vaccination record when the dose was actually administered; this could lead to over-immunization and would show as an incomplete dose on the patient record.

EXPECTATIONS:

- IIS shall forecast vaccines due next regardless of refused vaccines, recorded or not recorded. The perspective of the ACIP is that the patient still needs the scheduled vaccine.
- IIS shall store refusals if submitted.
- IIS shall not store refusals as contraindications.
- EHR systems shall not store refusals as contraindications.
- EHR systems should submit refusals if known.

EHR Systems
SHOULD SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARDS SUPPORTED:

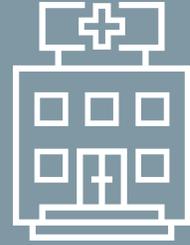
- **13.0** The IIS supports reporting and investigation of vaccine adverse events.
- **15.0** The IIS supports immunization-related efforts in school settings.
- **16.0** The IIS supports immunization-related efforts in childcare settings.
- **19.0** The IIS supports reminder and recall activities.



**GROUP:
FACILITY**

12





12 FACILITY

12.1 ADMINISTERED AT LOCATION



CDC DEFINITION: The facility name/identifier of the facility that administered the immunization. This information may not be available for a historical dose.

Administered at location represents the physical location where the patient received the immunization, such as the clinic or provider office. This may be a clinic that is part of a larger provider organization or an independent clinic. It is the location that is responsible for the inventory used for the administered vaccine. Depending upon the size and structure of the provider organization, this may be the same as the sending and/or responsible organization.

To ensure that this data can be leveraged by the IIS, for inventory decrementing or other activities, the value sent should be an ID supplied by the IIS.

IIS typically have complex processing rules to ensure that vaccination event records are updated or overwritten only when appropriate. See [MIROW Guide: Consolidating Demographic Records and Vaccination Event Records](https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/).⁴⁴



⁴⁴ <https://repository.immregistries.org/resource/consolidating-demographic-records-and-vaccination-event-records/>

CHALLENGES:

- The relationship between clinic location and larger provider organization can be challenging to differentiate and is typically clarified during the onboarding process. This distinction is especially important if any of the parties participate in the Vaccines for Children program and need to manage inventory separately.
- Similarly, the business needs for identifying administered at location, sending, and responsible organizations—versus clinics, departments, and cost centers—vary between IIS and EHRs. Unless it is very clear during an onboarding process how to map locations in the IIS to locations in the EHR, data quality issues may arise, such as attribution of doses to the correct provider organization or decrementing inventory. The more complex a provider organization or health system is, the more likely that each of the IIS organizations (provider, responsible, and sending) will be different.
- **If missing:** Vaccination events will not be associated with the correct provider organization. It could also preclude an active status from being attributed to the patient for the provider organization. Inventory decrementing could fail.
- **If inaccurate:** Vaccination events could be associated with the wrong provider organization, and inventory deduction might happen for the wrong provider’s inventory.

EXPECTATIONS:

- IIS shall store administered at location when submitted with administered doses.
- IIS may utilize administered at location as part of the vaccine inventory decrementing process and/or vaccine accountability activities.
- EHR systems shall submit administered at location ID (supplied by IIS) for vaccination events marked as administered.
- EHR systems may submit administered at location ID (supplied by IIS) for vaccination events marked as historical.

EHR Systems
SHALL SUBMIT
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARD SUPPORTED:

- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.

12.2 RESPONSIBLE ORGANIZATION



CDC DEFINITION: The identifier of the organization that originated and is accountable for the content of the record.

The responsible organization is responsible for and owns the data submitted to the IIS. It is the provider organization that sees the patient, administers vaccinations, and reports vaccination events to the IIS. The responsible organization may also be an entity that submits immunization history and/or patient demographics to the IIS but does not administer vaccinations, such as Vital Records or health plans.

A single entity may represent the responsible organization as well as the sending organization and the administered at location. The organizational layers of these concepts allow for the ownership and reporting of data by complex organizations. For example, a provider organization without any relationship to a larger group practice or health system may have its own EHR that fully manages sending data to the IIS. In this scenario, the provider organization plays all three roles: responsible organization, sending organization, and administered at location. In a separate example, a provider organization that is affiliated with a large health system and shares an instance of the health system's EHR is the responsible organization and administered at location. The health system is the sending organization.

CHALLENGES:

- The structure or hierarchy of departments, clinics, and practices within a health system may need to be drawn differently to support IIS functionality. For example, the organizational relationship chart in a health system may be designed to support underlying billing processes or business needs unrelated to immunizations. If that same health system has practices that participate in the VFC program or other, state-supplied vaccine programs, the organization chart may need to look different.
- **If missing:** Vaccination events will not be associated with the appropriate provider organization. It can also cause inventory decrementing to fail.
- **If inaccurate:** Vaccination events could be associated with the wrong provider organization, and inventory deduction might happen for the wrong provider's inventory. The data could be rejected if inaccurate and unrecognizable or unresolvable to the sending organization.

EXPECTATIONS:

- IIS shall assign a unique identifier to the responsible organization.
- IIS shall assign the responsible organization as the owner of the submitted doses. The owner may be the only provider organization that can delete or overwrite details about an administered vaccination event. Historical vaccination events can generally be updated by non-owner provider organizations.
- IIS should assign a one-to-one relationship between the VFC pin number and the responsible organization identifier.
- EHR systems shall submit responsible organization for all doses, whether administered or historical.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARD SUPPORTED:

- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.

12.3 SENDING ORGANIZATION



CDC DEFINITION: The identifier of the organization that connects to the IIS and submits the record.

The sending organization represents the entity that owns or operates the application used for sending data from the EHR to the IIS. This could be an umbrella organization for a health system, where all provider organizations (clinics, facilities, departments, ERs) are on the same EHR system. Data flows from provider-organization level to the health-system level and then to the IIS. Alternatively, the sending organization could be an EHR hub where multiple provider organizations pass through to the IIS but those provider organizations do not have a business relationship.

CHALLENGES:

- The structure or hierarchy of departments, clinics, and practices within a health system might need to be drawn differently to support IIS functionality. For example, the organizational relationship chart in a health system might be designed to support underlying billing processes or business needs unrelated to immunizations. If that same health system has practices that participate in the VFC program or other, state-supplied vaccine programs, the organization chart might need to look different.
- **If missing:** There might be no impact on incoming data if a sending organization does not exist in the trading partner’s organizational structure.
- **If inaccurate:** The IIS cannot resolve the relationship between the responsible and sending organizations.

EXPECTATIONS:

- IIS shall assign a unique identifier to the sending organization during the enrollment or onboarding process.
- IIS shall not assign ownership of reported doses to the sending organization, except where sending and responsible are the same organization.
- EHR systems shall submit sending organization if known.

EHR Systems
SHALL SUBMIT if known
Vital Records Systems
N/A

IIS FUNCTIONAL STANDARD SUPPORTED:

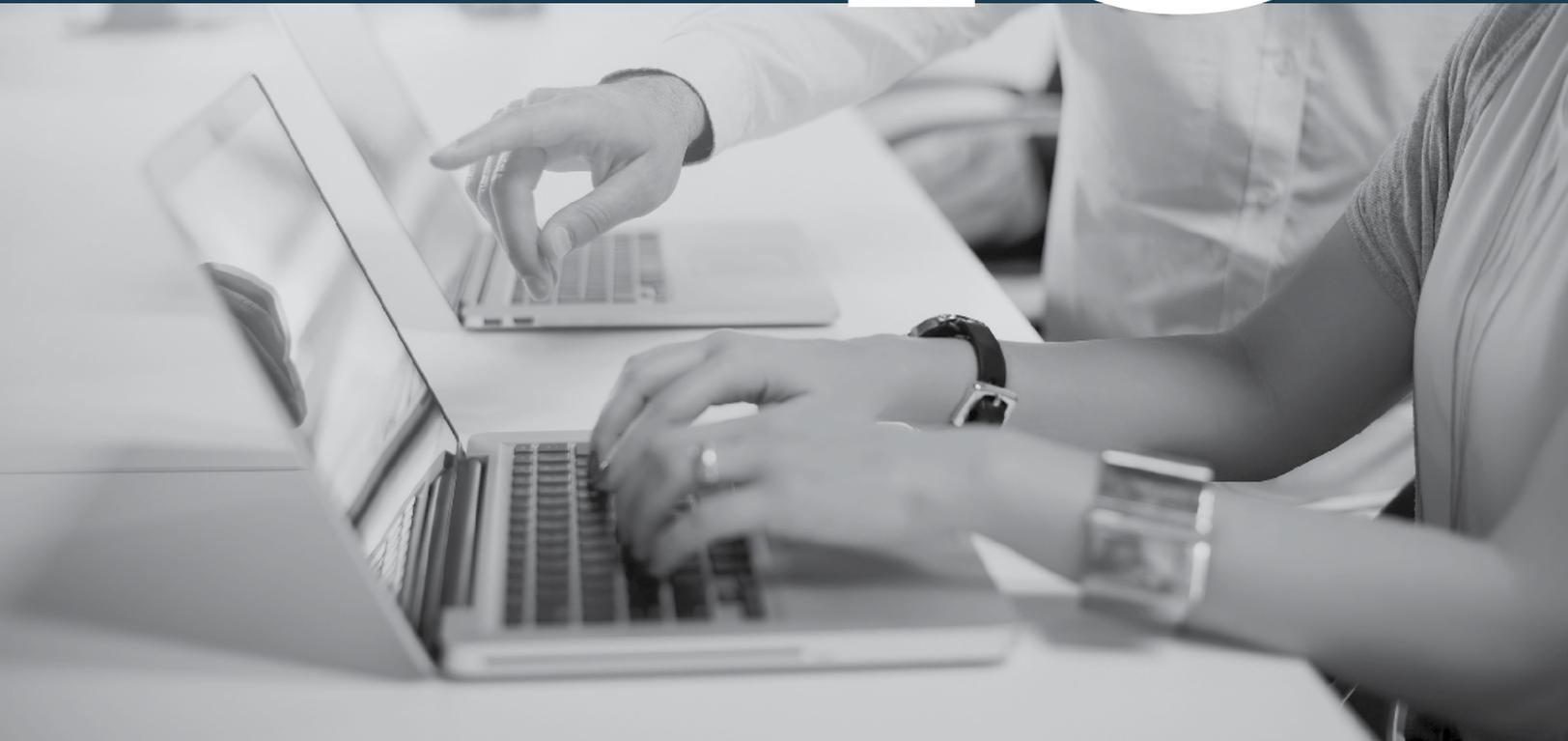
- **3.0** The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.





**LIMITATIONS
& GAPS**

13



13 LIMITATIONS & GAPS

This project uncovered a number of limitations and gaps that could not be addressed within the scope and time frame allotted for the current effort.

LIMITATIONS:

- Some data elements have different purposes depending on the data owner or trading partner type. An IIS may capture patient address to support matching processes and reminder/recall activities while an EHR system may capture patient address to have a billing contact on file. Similarly, responsible person has different purposes and definitions across trading partners. Capturing mother's name is valuable demographic data to aid in matching. However, the mother might or might not be the responsible person. This guide seeks to clarify these differences but, in most cases, cannot resolve them.
- Jurisdictional differences in policy and law mean that data elements such as protection indicator may be leveraged in different ways across jurisdictions.
- The workgroup found that some data elements had limited examples of practical use, such as patient birth state or vaccine information statements. While under specific scenarios these data elements may be desired, in general they are not used in the daily operations of an IIS.

GAPS:

- Limited time available in this project's timeline meant covering only prioritized data elements in detail. Future work may include reviewing all CDC Endorsed Data Elements.
- Some concepts and/or data elements need further exploration where the utility of the data element differs depending on the trading partner. While these distinctions do not necessarily need to align, the specific use cases by trading partner would benefit from being more fully explored and documented.
- Further exploration of priority value is warranted for some data elements, e.g., telephone number and which type(s) are preferred by IIS. The current code sets for telecommunication use and equipment are outdated. Similarly, exploration and prioritization of responsible person relationship types is needed to ensure consistent use and value to the community.
- Additional work is needed to explore solutions for maintaining patient status in the IIS for patients who have moved or gone elsewhere, as there is not currently a method for triggering updates to the IIS via HL7 data exchange when no immunization is administered or reported.

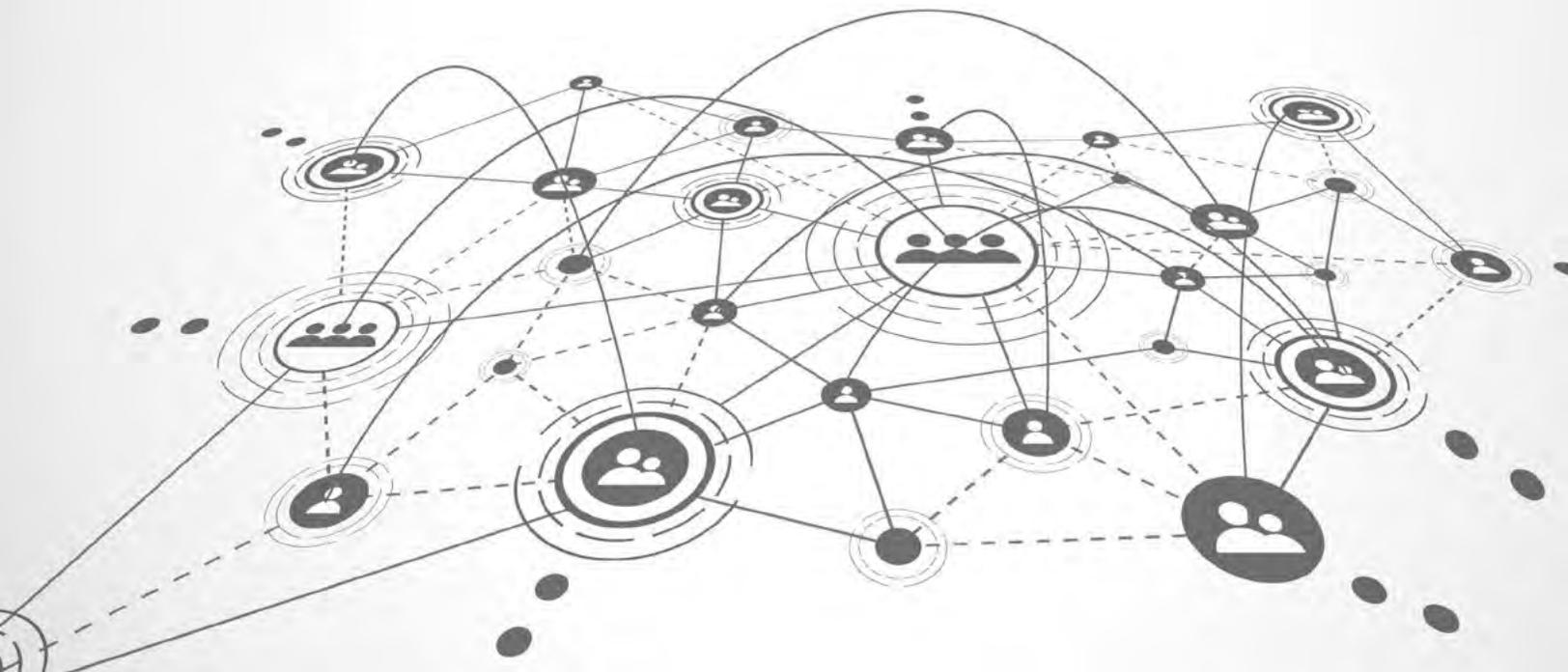
APPENDICES

APPENDIX A ABBREVIATIONS/ACRONYMS	88
---	-----------

APPENDIX B MASTER DATA ELEMENTS TABLE	89
---	-----------

APPENDIX C DATA ELEMENTS MAPPED TO FUNCTIONAL STANDARDS	95
--	-----------

APPENDIX D ACKNOWLEDGMENTS	101
--------------------------------------	------------



APPENDIX A. ABBREVIATIONS/ACRONYMS

ABBREVIATIONS/ACRONYMS	
ACIP	Advisory Committee on Immunization Practices
AIRA	American Immunization Registry Association
CDC	Centers for Disease Control and Prevention
CDS	Clinical Decision Support
CDSi	Clinical Decision Support for immunizations
CPT	Current Procedural Terminology
CVX	CDC Code for Vaccine Product
EDE	Electronic Data Exchange
EHR	Electronic Health Record
HL7	Health Level Seven International
HL7 IG	HL7 2.5.1 rel. 1.5 Implementation Guide and Addendum
IIS	Immunization Information System
MIROW	Modeling of Immunization Registry Operations Workgroup
MRN	Medical Record Number
MVX	CDC Code for Manufacturers of Vaccine
NDC	National Drug Code
NPI	National Provider Identifier
PHIN VADS	Public Health Information Network Vocabulary and Distribution System
SME	Subject Matter Expert
SSN	Social Security Number
VFC	Vaccines for Children program

APPENDIX B. MASTER DATA ELEMENTS TABLE

This table provides a snapshot of the expectations for trading partners exchanging data with IIS.

While EHR systems and Vital Records systems are specifically called out, these data exchange requirements apply to most primary (provider organizations, pharmacies, mass immunizers, etc.) and secondary submitters (health plans, Vital Records, etc.).

The HL7 IG column in the table below indicates the field level usage, as referenced in the HL7 IG at the time that this guide was published. The HL7 IG usage (R-required/RE-required but may be empty/O-optional/C-conditional) applies to the data element assuming the segment is sent in the message. For example, responsible person name is required per HL7 *if the Next of Kin (NK1) segment is included in the message*. The NK1 segment is not required. Similarly, PID-3 (patient identifier) is a required field for all HL7 messages, but IIS patient ID does not need to be one of the ID types sent in PID-3; other data elements can satisfy that requirement.

Further information on conditionality and field- and segment-level requirements are described in the HL7 IG.

DATA ELEMENT	DEFINITION/EXPLANATION	HL7 IG ⁴⁵	EHR SYSTEM	VITAL RECORDS SYSTEM
Patient Demographics				
Date of History of Disease/Titer	The date/time patient immunity due to serological or clinical evidence was observed.	RE (if History sent)	Should submit if known	N/A
Ethnicity	The ancestry of the patient.	RE	Shall submit if known	Shall submit if known
History of Disease/Titer	The disease the patient is expected to be immune to on the basis of serological or clinical evidence.	O	Should submit if known	N/A

⁴⁵ Key: R/required, RE/required but may be empty, O/optional.

DATA ELEMENT	DEFINITION/EXPLANATION	HL7 IG ⁴⁵	EHR SYSTEM	VITAL RECORDS SYSTEM
IIS Patient ID	The unique identifier assigned by IIS to each patient.	0	N/A	N/A
Mother's Name: First	The first name of the patient's mother.	0	Should submit if known	May submit
Mother's Name: Last	The last name of the patient's mother.	0	Should submit if known	May submit
Mother's Name: Maiden Last	The last name under which the mother was born (i.e., before marriage).	RE	Shall submit if known	May submit
Mother's Name: Middle	The middle name of the patient's mother.	0	Should submit if known	May submit
Patient Address: County of Residence	The county component of the patient's address.	0	May submit	May submit
Patient Address: City	The city component of the patient's address.	RE	Shall submit if known	May submit
Patient Address: Country	The country component of the patient's address.	RE	Shall submit if known	May submit
Patient Address: State	The state component of the patient's address.	RE	Shall submit if known	May submit
Patient Address: Street	The street component of the patient's address.	RE	Shall submit if known	May submit
Patient Address: Zip Code	The ZIP code of the patient's address.	RE	Shall submit if known	May submit
Patient Alias Name: First	The first name of a patient's alternate or also-known-as name.	0	Should submit if known	N/A
Patient Alias Name: Last	The last name of a patient's alternate or also-known-as name.	0	Should submit if known	N/A
Patient Alias Name: Middle	The middle name of a patient's alternate or also-known-as name.	0	Should submit if known	N/A

DATA ELEMENT	DEFINITION/EXPLANATION	HL7 IG ⁴⁵	EHR SYSTEM	VITAL RECORDS SYSTEM
Patient Birth Order	When a patient was part of a multiple birth, a number is defined in this element.	RE (if multiple)	Shall submit if known	Shall submit
Patient Birth State	State of the birthing facility location.	O	May submit	Shall submit
Patient Date of Birth	The patient's date of birth.	R	Shall submit	Shall submit
Patient E-mail Address	The patient's email address.	O	Should submit if known	N/A
Patient Gender	The patient's gender.	R	Shall submit	Shall submit
Patient ID	Unique identifier assigned by IIS-AO (data source) to each patient.	R	Shall submit	Shall submit
Patient ID: Type	The ID type (e.g., medical record number, birth certificate ID, etc.) of the associated patient ID.	R	Shall submit	Shall submit
Patient Multiple Birth Indicator	Whether the patient was part of a multiple birth (yes/no).	RE	Shall submit if known	Shall submit
Patient Name: First	The patient's first name.	R	Shall submit	Shall submit
Patient Name: Last	The patient's last name.	R	Shall submit	Shall submit
Patient Name: Middle	The patient's middle name.	RE	Shall submit if known	Shall submit
Patient Primary Language	The patient's primary language.	O	Should submit if known	N/A
Patient Status Indicator–Provider Level	The current active/inactive status of the patient in relation to the provider organization.	RE	Shall submit if known	N/A
Patient Status–Jurisdiction Level	The patient/geographic jurisdiction status determined from address information.	N/A	N/A	N/A
Patient Telephone Number	The patient's phone number.	RE	Shall submit if known	N/A
Patient Telephone Number Type	The type of phone number (e.g., home, cell) for each patient telephone number.	R	Shall submit	N/A
Protection Indicator	Whether a person's information may be shared with others, as defined locally.	RE	Shall submit if known	N/A

DATA ELEMENT	DEFINITION/EXPLANATION	HL7 IG ⁴⁵	EHR SYSTEM	VITAL RECORDS SYSTEM
Protection Indicator Effective Date	The effective date for the protection indicator.	RE (if indicated)	Shall submit if known	N/A
Race	The patient's race.	RE	Shall submit if known	Shall submit
Reminder/Recall Effective Date	The effective date for the patient's reminder/recall status.	RE (if indicated)	Shall submit if known	N/A
Reminder/Recall Status	Whether or not a person wishes to be contacted in a reminder or recall situation.	RE	Shall submit if known	N/A
Responsible Person Name: First	The first name of the person responsible for the patient.	R	Shall submit	N/A
Responsible Person Name: Last	The last name of the person responsible for the patient.	R	Shall submit	N/A
Responsible Person Name: Middle	The middle name of the person responsible for the patient.	RE	Shall submit if known	N/A
Responsible Person Relationship to Patient	The actual personal relationship that the responsible person has to the patient.	R	Shall submit	N/A
Vaccination Event				
Administered at Location	The facility name/identifier of the facility that administered the immunization.	RE (if administered dose)	Shall submit	May submit
Contraindications/Precautions	A reason(s) to consider not giving a patient a vaccine proposed for administration.	O	Should submit if known	N/A
Contraindications/Precautions Observation Date	The date/time the patient contraindication or precaution was observed.	RE (if indicated)	Shall submit if known	N/A
Dose Level Eligibility	The program that should pay for a given immunization, based on the characteristics of the patient and the type of vaccine administered.	RE (if administered dose)	Shall submit if known	N/A
Exemptions/Refusals Date	The date that the refusal or deferral was recorded.	RE (if indicated)	Shall submit if known	N/A

DATA ELEMENT	DEFINITION/EXPLANATION	HL7 IG ⁴⁵	EHR SYSTEM	VITAL RECORDS SYSTEM
Exemptions/Refusals Reason	The reason for an exemption/refusal.	RE (if indicated)	Should submit if known	N/A
IIS Vaccination Event ID	The unique identifier assigned by IIS to each vaccination event.	N/A	N/A	N/A
Responsible Organization	The identifier of the organization that originated and is accountable for the content of the record.	RE	Shall submit if known	May submit
Sending Organization	The identifier of the organization that connects to the IIS and submits the record.	RE	Shall submit if known	May submit
Vaccination Administration Date	The date the vaccination event occurred.	R	Shall submit	Shall submit
Vaccination Event ID	The vaccination event's unique identifier assigned by the submitting system.	R	Should submit	N/A
Vaccination Event Record Type	Indicates whether the vaccination event is based on a historical record or was given by the administered at location.	R	Shall submit	Shall submit
Vaccine Administering Provider	The name of the provider (person) administering the vaccination.	RE (if administered dose)	Shall submit if known	N/A
Vaccine Administering Provider Suffix	The professional designation of the person administering the vaccination.	O	Should submit if known	N/A
Vaccine Dose Volume	The amount of vaccine administered (e.g., .5).	R	Shall submit	N/A
Vaccine Dose Volume Units	The unit of measure of the dose (e.g., ml). Note: Based on local need, this may include immunoglobulin or other medical substances.	R (if administered dose)	Shall submit	N/A
Vaccine Expiration Date	The expiration date of the vaccine administered.	RE (if administered dose)	Shall submit if known	N/A
Vaccine Funding Source	The funding source of the vaccine administered.	RE (if administered dose)	Shall submit if known	N/A

DATA ELEMENT	DEFINITION/EXPLANATION	HL7 IG ⁴⁵	EHR SYSTEM	VITAL RECORDS SYSTEM
Vaccine Information Statement	The publication date of the Vaccine Information Statement.	RE (if primary record)	Shall submit if known	N/A
Vaccine Information Statement Given Date	The date the VIS information was provided to the patient.	RE (if primary record)	Shall submit if known	N/A
Vaccine Lot Number	The lot number of the vaccine administered.	R (if administered dose)	Shall submit	N/A
Vaccine Manufacturer Name	The manufacturer of the vaccine that was administered.	R (if administered dose)	Shall submit	N/A
Vaccine Ordering Provider	The identifier of the provider (person) ordering the immunization.	RE (if administered dose)	Shall submit if known	N/A
Vaccine Product	The vaccine type that may be administered, historical, or refused, and is messaged using the NDC or CVX code sets.	R	Shall submit	Shall submit if known
Vaccine Route of Administration	The route of administration.	R	Shall submit	N/A
Vaccine Site of Administration	The anatomical site where the vaccine was given.	RE	Shall submit if known	N/A



APPENDIX C. DATA ELEMENTS MAPPED TO FUNCTIONAL STANDARDS

The table of IIS Functional Standards and CDC Endorsed Data Elements below is a snapshot of the crosswalk published with the [CDC Endorsed Data Elements](#).⁴⁶ IIS Functional Standards 1, 4–7, 9, and 21 apply to all data elements.

IIS FUNCTIONAL STANDARD	CDC ENDORSED DATA ELEMENT
<p>2.0 The IIS identifies, prevents, and resolves duplicated and fragmented patient records using an automated process.</p>	<ul style="list-style-type: none"> • Ethnicity • IIS Patient ID • Mother’s Name: First • Mother’s Name: Last • Mother’s Name: Maiden Last • Mother’s Name: Middle • Patient Address: County of Residence • Patient Address: City • Patient Address: Country • Patient Address: State • Patient Address: Zip • Patient Alias Name: First • Patient Alias Name: Last • Patient Alias Name: Middle • Patient Birth Order • Patient Birth State • Patient Date of Birth • Patient Gender • Patient ID • Patient ID: Type • Patient Multiple Birth Indicator • Patient Name: First • Patient Name: Last • Patient Name: Middle • Responsible Person Name: First • Responsible Person Name: Last • Responsible Person Name: Middle • Responsible Person Relationship to Patient

⁴⁶ <https://www.cdc.gov/vaccines/programs/iis/core-data-elements/iis-func-stds.html>

IIS FUNCTIONAL STANDARD	CDC ENDORSED DATA ELEMENT
<p>3.0 The IIS identifies, prevents, and resolves duplicate vaccination events using an automated process.</p>	<ul style="list-style-type: none"> • IIS Patient ID • Patient ID • Patient ID: Type • Administered at Location • Responsible Organization • Sending Organization • Vaccination Administration Date • Vaccination Event Record Type • Vaccine Administering Provider • Vaccine Administering Provider Suffix • Vaccine Lot Number • Vaccine Ordering Provider • Vaccine Product
<p>4.0 The IIS implements written and approved confidentiality policies that protect the privacy of individuals whose data are contained in the system.</p>	<ul style="list-style-type: none"> • Protection Indicator • Protection Indicator Effective Date
<p>8.0 The IIS exchanges data with health information systems in accordance with current interoperability standards endorsed by CDC for message content, format, and transport.</p>	<ul style="list-style-type: none"> • Patient Date of Birth • Patient Name: First • Patient Name: Last • Patient Name: Middle • IIS Vaccination Event ID • Vaccination Administration Date • Vaccination Event ID • Vaccine Dose Volume • Vaccine Dose Units • Vaccine Information Statement • Vaccine Information Statement Given Date • Vaccine Manufacturer Name

IIS FUNCTIONAL STANDARD	CDC ENDORSED DATA ELEMENT
<p>10.0 The IIS forecasts pediatric, adolescent, and adult immunizations in a manner consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.</p>	<ul style="list-style-type: none"> • Date of History of Disease/Titer • History of Disease/Titer • IIS Patient ID • Patient Gender • Patient Name: First • Patient Name: Last • Patient Name: Middle • Contraindications/Precautions • Contraindications/Precautions Observation Date • Exemptions/Refusals Date • IIS Vaccination Event ID • Vaccination Administration Date • Vaccination Event ID • Vaccine Dose Volume • Vaccine Dose Volume Units • Vaccine Expiration Date • Vaccine Manufacturer Name • Vaccine Product
<p>11.0 The IIS manages patient status at the provider organization and jurisdiction levels.</p>	<ul style="list-style-type: none"> • Patient Address: County of Residence • Patient Address: City • Patient Address: Country • Patient Address: State • Patient Address: Zip • Patient Status Indicator – Provider Level • Patient Status Indicator – Jurisdiction Level
<p>12.0 The IIS supports vaccine product recall activities.</p>	<ul style="list-style-type: none"> • Patient Address: State • Patient Address: Zip • Vaccine Lot Number • Vaccine Manufacturer Name • Vaccine Product

IIS FUNCTIONAL STANDARD	CDC ENDORSED DATA ELEMENT
<p>13.0 The IIS supports reporting and investigation of vaccine adverse events.</p>	<ul style="list-style-type: none"> • Patient Address: County of Residence • Patient Address: City • Patient Address: Country • Patient Address: State • Patient Address: Zip • Patient Date of Birth • Patient Name: First • Patient Name: Last • Patient Name: Middle • Contraindications/Precautions • Contraindications/Precautions Observations Date • Exemptions/Refusals Reason • Vaccination Administration Date • Vaccine Lot Number • Vaccine Manufacturer Name • Vaccine Product • Vaccine Route of Administration • Vaccine Site of Administration
<p>14.0 The IIS supports public health response during disease outbreaks.</p>	<ul style="list-style-type: none"> • Date of History of Disease/Titer • History of Disease/Titer • IIS Patient ID • Patient Address: City • Patient Address: Country • Patient Address: State • Patient Address: Zip • Patient Name: First • Patient Name: Last • Patient Name: Middle • Vaccine Lot Number
<p>15.0 The IIS supports immunization-related efforts in school settings.</p>	<ul style="list-style-type: none"> • Date of History of Disease/Titer • History of Disease/Titer • IIS Patient ID • Mother's Name: First • Mother's Name: Last • Patient Address: City • Patient Address: State • Patient Address: Zip • Patient Name: First • Patient Name: Last • Patient Name: Middle • Exemptions/Refusals Reason

IIS FUNCTIONAL STANDARD	CDC ENDORSED DATA ELEMENT
<p>16.0 The IIS supports immunization-related efforts in childcare settings.</p>	<ul style="list-style-type: none"> • Date of History of Disease/Titer • History of Disease/Titer • IIS Patient ID • Mother’s Name: First • Mother’s Name: Last • Patient Address: City • Patient Address: State • Patient Address: Zip • Patient Name: First • Patient Name: Last • Patient Name: Middle • Exemptions/Refusals Reason
<p>17.0 The IIS supports immunization program activities during a public health emergency according to the jurisdiction’s public health emergency plan.</p>	<ul style="list-style-type: none"> • Date of History of Disease/Titer • History of Disease/Titer • Patient Address: City • Patient Address: Country • Patient Address: State • Patient Address: Zip • Patient Name: First • Patient Name: Last • Patient Name: Middle
<p>18.0 The IIS provides predefined and ad hoc assessment and coverage reports that users can generate without assistance from the IIS.</p>	<ul style="list-style-type: none"> • Ethnicity • Mother’s Name: First • Mother’s Name: Last • Patient Address: County of Residence • Patient Address: City • Patient Address: Country • Patient Address: Zip • Patient Gender • Patient Name: First • Patient Name: Last • Patient Name: Middle • Patient Status Indicator – Provider Level • Patient Status Indicator – Jurisdiction Level • Race • Contraindications/Precautions

IIS FUNCTIONAL STANDARD	CDC ENDORSED DATA ELEMENT
<p>19.0 The IIS supports reminder and recall activities.</p>	<ul style="list-style-type: none"> • Patient Address: County of Residence • Patient Address: City • Patient Address: Country • Patient Address: State • Patient Address: Zip • Patient E-mail Address • Patient Name: First • Patient Name: Middle • Patient Primary Language • Patient Status Indicator – Jurisdiction Level • Patient Telephone Number • Patient Telephone Number Type • Reminder/Recall Effective Date • Reminder/Recall Status • Contraindications/Precautions • Exemptions/Refusals Reason • IIS Vaccination Event ID
<p>20.0 The IIS provides immunization records to individuals with appropriate authentication.</p>	<ul style="list-style-type: none"> • Patient Date of Birth
<p>23.0 The IIS supports vaccine management and quality assurance functions for VFC and state and local vaccine programs.</p>	<ul style="list-style-type: none"> • Race
<p>25.0 The IIS supports provider-site level vaccine inventory management and reconciliation according to VFC and state and local immunization program requirements.</p>	<ul style="list-style-type: none"> • Dose Level Eligibility • Vaccination Administration Date • Vaccine Funding Source • Vaccine Lot Number • Vaccine Manufacturer Name • Vaccine Product
<p>26.0 The IIS provides data or produces reports for VFC and state and local immunization programs.</p>	<ul style="list-style-type: none"> • Patient Date of Birth • Race • Vaccine Funding Source • Vaccine Information Statement • Vaccine Information Statement Given Date • Vaccine Lot Number • Vaccine Manufacturer Name • Vaccine Product

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